Page 1 of 166

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DR. HARVEY RISCH - 1

CASE NO. 2:24-cv-01673-TL

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- 2. I was the Lead for the Medical-Technical Team for UW Medicine's COVID-19 Emergency Operations Center ("EOC") from February 2020 until December 2023, when the Medical-Technical Team was no longer required. In that capacity, I helped guide UW Medicine's response to the COVID-19 pandemic, including with respect to UW Medicine's decision and policy to require COVID-19 vaccinations for its clinical employees.
- 3. I earned my Doctor of Medicine ("MD") from the UW School of Medicine in 2002 and my Master's in Public Health ("MPH") in epidemiology and global health from the UW School of Public Health in 2011. After completing my internship and residency in internal medicine at the Massachusetts General Hospital in 2005, I did my clinical fellowship in infectious diseases at the UW School of Medicine (2005–2009) and was a post-doctoral fellow in viral immunology in the laboratory of Dr. Julie Overbaugh at the Fred Hutchinson Cancer Research Center (now the Fred Hutchinson Cancer Center). I am an active teacher and have a long history of providing infectious diseases education for students, residents, fellows, physicians, nurses, pharmacists, many other types of healthcare workers, and the public.
- 4. A copy of my CV, which contains additional information regarding my qualifications and a list of publications I authored or co-authored, is attached as to this declaration as **Exhibit A**.

I. FACTS OR DATA CONSIDERED

- 5. In addition to the medical studies, public health data, and news reports cited herein and knowledge I have gained in my decades of working in clinical infectious diseases, infectious disease research, public health, and epidemiology, I considered the following materials in forming the opinions set forth in this declaration:
 - City of Issaquah (the "City") Administrative Order, Update: COVID-19
 (Coronavirus) Protection Plan & Policy Updates August 10 and 20, 2021

DECLARATION OF JOHN LYNCH, MD IN SUPPORT OF DEFENDANT CITY OF ISSAQUAH'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE DR. HARVEY RISCH - 2 CASE NO. 2:24-cv-01673-TL

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- State of Washington, Office of the Governor, Proclamation by the Governor 21-14.4.¹
- City of Issaquah Police Officer Position Description.
- Cheyanne Dixon's religious accommodation request form.
- October 1, 2021 letter to Cheyanne Dixon from Stephanie Johnson regarding her request for accommodation.
- October 15, 2021 letter to Cheyanne Dixon from Stephanie Johnson regarding additional safety protocols during the limited extension period.
- October 18-19, 2021 email chain between Cheyanne Dixon, Lauren Knox, Scott Behrbaum, and Paula Schwan regarding Plaintiff's request for accommodation.
- October 19, 2021 email chain between Scott Behrbaum and Paula Schwan regarding COVID Testing Oversight for Supervisors.
- January 5-6, 2022 email chain between Cheyanne Dixon, Stephanie Johnson, and Paula Schwan regarding COVID testing.
- February 2, 2022 Notice of Intent to Separate Employment to Cheyanne Rosa from Wally Bobkiewicz.
- February 14, 2022 Letter regarding separation of employment to Cheyanne Rosa from Mayor Pauly.
- The Memorandum of Understanding between the City and the Issaquah Police Officers' Association related to COVID-19.
- Deposition of Cheyanne Dixson, Dixson v. Issaquah, August 30, 2023, and exhibits used during the deposition.
- The declarations submitted in support of and in opposition to the Issaquah Police Department's Motion for Summary Judgment in *Dixson v. Issaquah Police Department*, Case No. 2-22-cv-01771-RAJ.
- 6. I have also toured the Issaquah Police Department and Issaquah City Jail and reviewed photos of the same and officers' cars.

¹ See https://governor.wa.gov/sites/default/files/proclamations/21-14.4%20-%20COVID-19%20Vax%20WA%20Amendment%20%28tmp%29.pdf.

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7. COVID-19 is an infectious disease that can result in serious illness or death. It is caused by the SARS-CoV-2 virus, which is a novel coronavirus not identified in humans prior to December 2019 that spreads easily from person to person.

- 8. As I describe in more detail later in this declaration, the COVID-19 virus has continued to evolve since it was first discovered in December 2019. As a result, there have been (and continue to be) many variants of the virus, with each new variant more infectious than those prior. While these variants have different characteristics, some characteristics have remained consistent across the variants that have developed since December 2019. These characteristics include:
 - COVID-19 spreads mainly from person to person through very small airborne respiratory droplets, usually referred to as aerosols, which are produced when an infected person exhales, coughs, sneezes, or talks.
 - There is a delay of at least a few days after exposure and infection before onset of symptoms.
 - People can spread the virus before their symptoms begin (pre-symptomatic transmission) and during an asymptomatic infection which results in people unknowingly spreading the virus to others. This is similar to other respiratory viruses like influenza.
 - Although many patients experience mild to moderate symptoms, or no symptoms, some patients experience severe or critical illness requiring hospitalization and intensive care treatment, such as the use of ventilators (intubation).
 - A subset of those with severe disease will die. As of January 16, 2025, over 1.2 million people in the U.S. have died due to COVID-19.² More than 16,200 have died in Washington State.
 - Older adults and people of any age with certain underlying medical conditions are at higher risk for severe COVID-19 illness.

² See U.S. Center for Disease Control and Prevention (CDC) National Center for Health Statistics, *Provisional COVID-19 Mortality Surveillance*, https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm.

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- Some COVID-19 survivors experience long-term health complications (sometimes called "long COVID"). These complications include the development of chronic symptoms including debilitating fatigue and body system abnormalities affecting the brain, heart, lungs, and other systems.
- 9. On January 20, 2020, the U.S. Centers for Disease Control & Prevention ("CDC") and the Washington State Department of Health ("DOH") announced what was then believed to be the first confirmed case of COVID-19 in the United States in Snohomish County, Washington.^{3, 4} By late February/early March, public health officials recognized the spread of COVID-19 in Washington, including an individual with COVID-19 from Snohomish County who had not traveled, and an outbreak in the Life Care Center, a skilled nursing facility in Kirkland, associated with at least 167 cases and 43 deaths.⁵ On February 29, 2020, DOH announced that a patient had died in the Evergreen Health Medical Center in Kirkland, which was then believed to be the first COVID-19 death in the United States. (In April 2020, it was determined that the first known COVID-19 death had occurred in early February in California.)⁶

³ See CDC, CDC Museum COVID-19 Timeline, Mar. 14, 2023, https://www.cdc.gov/museum/timeline/covid19.html.

⁴ See Heather P. McLaughlin, et al., COVID-19 Response Efforts of Washington State Public Health Laboratory: Lessons Learned, 111(5) Am. J. Public Health 867 (May 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8034017/.

⁵ See Asia Fields & Paige Cornwell, Coronavirus killed hundreds at Washington state's long-term care facilities. Widespread testing may finally be near, Seattle Times, Apr. 18, 2020, https://www.seattletimes.com/seattle-news/coronavirus-killed-hundreds-at-washington-states-long-term-care-facilities-six-weeks-later-widespread-testing-may-finally-near/ (updated May 8, 2020).

⁶ See Thomas Fuller & Mike Baker, Coronavirus Death in California Came Weeks Before First Known U.S. Death, N.Y. Times (updated May 7, 2020), https://www.nytimes.com/2020/04/22/us/coronavirus-first-united-states-death.html.

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- 11. Over the course of 2020, public health measures designed to limit the spread of COVID-19 (*e.g.*, "lockdown" or "stay at home" policies, masking and testing requirements, and social distancing measures) caused enormous disruption to life and work in the United States and Washington State.
- 12. Since COVID-19 was first detected in the United States, it has disproportionately affected—both in terms of numbers of infections and numbers of severe cases leading to hospitalizations—certain groups, including the elderly, those with underlying health conditions, and incarcerated individuals. The Washington State Respiratory Illness Dashboard tracked outcomes for Washington residents by region throughout the pandemic, including hospitalizations and deaths due to COVID-19 in different demographic groups. In King County, for example, for people aged 65 or older, the hospitalization rate for COVID was 18.4 per 100,000 individuals, compared to less than 10 per 100,000 for all other younger age groups. Similarly, the death rate for

DECLARATION OF JOHN LYNCH, MD IN SUPPORT OF DEFENDANT CITY OF ISSAQUAH'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE DR. HARVEY RISCH - 6 CASE NO. 2:24-cv-01673-TL

⁷ See World Health Organization, WHO Director-General's statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV), January 30, 2020, https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ihr-emergency-committee-on-novel-coronavirus-(2019-ncov). The World Health Organization declared that COVID-19 was an established and ongoing health issue which no longer constitutes a public health emergency of international concern on May 5, 2023.

⁸ See World Health Organization, Statement on the fifteenth meeting of the IHR (2005) Emergency Committee on the COVID-19 pandemic, May 5, 2023, <a href="https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic.

⁹ See Administration for Strategic Preparedness and Response, *Determination That a Public Health Emergency Exists*, Jan. 31, 2020, https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx. The federal public health emergency expired on May 11, 2023.

¹⁰ See Department of Health and Human Services, HHS Secretary Xavier Becerra Statement on End of COVID-19 Public Health Emergency, May 11, 2023, https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.

¹¹ See Lewis NM, Salmanson AP, Price A, Risk I, Guymon C, Wisner M, Gardner K, Fukunaga R, Schwitters A, Lambert L, Baggett HC, Ewetola R, Dunn AC. Community-Associated Outbreak of COVID-19 in a Correctional Facility - Utah, September 2020-January 2021. MMWR Morb Mortal Wkly Rep. 2021 Apr 2;70(13):467-472. doi: 10.15585/mmwr.mm7013a2. PMID: 33793464; PMCID: PMC8022878.

those 65 years and older was 4.2 per 100,000, compared to less than 1 per 100,000 for the other age groups. 12 These rates were consistent with trends elsewhere in Washington and nationally. 13 In the United States as a whole, in January 2021, the COVID-19 hospitalization rate peaked at 21 per 100,000 people and, after a decrease, rose again to 12.6 per 100,000 people in July 2021. Those over 65 years of age were disproportionately impacted in all areas of the US. 14 COVID-19 also disproportionately affected members of certain racial and ethnic groups including Black, Hispanic, American Indian/Alaska Native, and Native Hawaiian/Pacific Islander. 15 These disproportional impacts have been seen both nationally and in Washington State. 16,17 Low-income populations and those experiencing disabilities have also been disproportionately impacted by COVID-19, especially those with underlying medical conditions or experiencing systemic health and social inequalities. 18, 19

13. There was (and remains) wide consensus among public health officials that developing an effective COVID-19 vaccine was crucial to returning to some semblance of "normal life."

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DECLARATION OF JOHN LYNCH, MD IN SUPPORT OF DEFENDANT CITY OF ISSAQUAH'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE DR. HARVEY RISCH - 7 CASE NO. 2:24-cv-01673-TL

¹² See https://kingcounty.gov/en/dept/dph/health-safety/disease-illness/covid-19/data/covid-summary.

¹³ See https://data.cdc.gov/Public-Health-Surveillance/Rates-of-COVID-19-Cases-or-Deaths-by-Age-Group-and/3rge-nu2a/about data.

¹⁴ See https://covid.cdc.gov/covid-data-tracker/?ref=quillette.com#covidnet-hospitalization-network.

¹⁵ Ibid.

¹⁶ See Don Bambino Geno Tai, et al., Disproportionate Impact of COVID-19 on Racial and Ethnical Minorities in the United States: a 2021 Update, 9 Journal of Racial and Ethnic Health Disparities 2022, 2334-39, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8513546/.

¹⁷ See Public Health – Seattle & King County, COVID-19 race and ethnicity data, Feb. 21, 2024, https://kingcounty.gov/en/legacy/depts/health/covid-19/data/race-ethnicity.

¹⁸ See Blair Whittington, Disparities in COVID-19 Hospitalization at the Intersection of Race and Ethnicity and Income, 11 Journal of Racial and Ethnic Health Disparities 2, 1116-23 (Apr. 2023), https://www.cdc.gov/mmwr/volumes/72/wr/mm7226a5.htm.

¹⁹ See CDC, People With Disabilities, https://www.cdc.gov/ncbddd/humandevelopment/covid-19/people-with-disabilities.html (updated July 20, 2022).

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III. VACCINE DEVELOPMENT, EFFECTIVENESS, AND FDA APPROVAL

- 14. Scientists began developing COVID-19 vaccines in January of 2020. Recognizing the severe impact of COVID-19 worldwide and drawing on significant work from before the COVID-19 emergency was declared, scientists were able to develop safe, reliable, COVID-19 vaccines with unprecedented speed.²⁰
- 15. On December 11, 2020, the U.S. Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for the use of Pfizer and BioNTech's COVID-19 vaccine (the "Pfizer vaccine").
- 16. On December 18, 2020, the FDA issued an EUA for Moderna TX, Inc.'s COVID-19 vaccine (the "Moderna vaccine").
- 17. On February 27, 2021, the FDA issued an EUA for the use of the Janssen (Johnson & Johnson) COVID-19 Vaccine (the "J&J vaccine").
- 18. The Pfizer and Moderna vaccines are messenger RNA ("mRNA") vaccines, which teach human cells how to make a SARS-CoV-2 virus "spike protein" which elicits a protective immune response and protects the body against future COVID-19 infection. These vaccines use the normal processes in our cells to make these proteins. Genetic information encoded in our cells' DNA is transferred to mRNA, which is used as a template for protein production. Importantly, the process cannot go in the other direction. This means that the vaccine mRNA cannot go into the nuclei of our cells where our DNA is located, nor can the mRNA be incorporated into our DNA. Like all our mRNA, the vaccine mRNA participates in making thousands of copies of the spike protein before it is degraded as part normal cell activities. The spike proteins are then trafficked to the cell surface where our immune cells can detect them and go on to develop a specific immune response that will be ready if the person is later exposed to the SARS-CoV-2 virus. This latter effect is the same pathway for all vaccines regardless of the technology that is used.

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²⁰ See National Institutes of Health, Decades in the Making: MRNA COVID-19 Vaccines, https://covid19.nih.gov/nih-strategic-response-covid-19/decades-making-mrna-covid-19-vaccines.

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20. The J&J vaccine is an adenovirus-based vaccine. It is a viral vector vaccine that uses a weakened live virus (*i.e.*, an adenovirus) as the delivery method for transporting a recombinant vaccine for COVID-19. Recombinant vaccines use a small piece of genetic material

²¹ See Nobel Prize, Press Release, Oct. 2, 2023, https://www.nobelprize.org/prizes/medicine/2023/press-release/. The Nobel Prize Committee's Press Release announcing the award describes the 2005 breakthrough the ultimately led to the mRNA vaccines:

[&]quot;Karikó and Weissman noticed that dendritic cells recognize *in vitro* transcribed mRNA as a foreign substance, which leads to their activation and the release of inflammatory signaling molecules. They wondered why the in *vitro* transcribed mRNA was recognized as foreign while mRNA from mammalian cells did not give rise to the same reaction. Karikó and Weissman realized that some critical properties must distinguish the different types of mRNA.

RNA contains four bases, abbreviated A, U, G, and C, corresponding to A, T, G, and C in DNA, the letters of the genetic code. Karikó and Weissman knew that bases in RNA from mammalian cells are frequently chemically modified, while *in vitro* transcribed mRNA is not. They wondered if the absence of altered bases in the *in vitro* transcribed RNA could explain the unwanted inflammatory reaction. To investigate this, they produced different variants of mRNA, each with unique chemical alterations in their bases, which they delivered to dendritic cells. The results were striking: The inflammatory response was almost abolished when base modifications were included in the mRNA. This was a paradigm change in our understanding of how cells recognize and respond to different forms of mRNA. Karikó and Weissman immediately understood that their discovery had profound significance for using mRNA as therapy. These seminal results were published in 2005, fifteen years before the COVID-19 pandemic."

- 21. EUAs are used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing or treating a disease. In determining whether to issue an EUA for a vaccine, the FDA evaluates the available evidence and assesses any known or potential risks and any known or potential benefits of the vaccine. If the risk-benefit assessment is favorable, the vaccine is made available during the public health emergency. For the COVID-19 vaccines, the agency evaluated data submitted by the manufacturers about the vaccine's safety and effectiveness, and conducted its own analyses, before reaching each decision and found the data to be "clear and compelling" to support the use of the vaccine for the prevention of COVID-19.²²
- 22. The FDA's evaluation of the Pfizer vaccine's safety included approximately 38,000 participants who enrolled in an ongoing, randomized, placebo-controlled international study, the majority of whom were U.S. participants. These participants, 18,801 of whom received the vaccine and 18,785 of whom received a saline placebo, were followed for a median of two months after receiving the second dose. The most reported side effects, which typically lasted several days, were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever. The trials "did not raise any specific safety concerns." Efficacy in preventing confirmed COVID-19 cases was 95.0%, with 8 COVID-19 cases in the vaccine group and 162 COVID-19 cases in the placebo group.²⁴
- 23. The FDA's evaluation of the Moderna vaccine's safety and efficacy included a randomized, double-blinded, and placebo-controlled trial of approximately 30,400 participants.

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²² See FDA, The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines#eua-vaccines.

²³ See FDA, Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum: Pfizer-BioNTech COVID-19 Vaccine (Dec. 11, 2020), https://www.fda.gov/media/144416/download.

²⁴ *Ibid*. at 9.

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- 24. The FDA's evaluation of the J&J vaccine included a randomized, double-blinded, and placebo-controlled trial of a single dose of the vaccine in approximately 40,000 participants. Efficacy in preventing COVID-19 cases occurring at least 14 days after the single-dose vaccination was 66.9%. Safety analysis supported a favorable safety profile with no specific safety concerns identified that would preclude the issuance of an EUA. The most common adverse reactions were injection site pain, headache, fatigue, and myalgia. Although the J&J vaccine can in rare cases cause a serious type of blood clots, they have occurred in fewer than one in a million cases. This rare but serious side effect led the FDA in May 2022 to modify its EUA for the J&J vaccine to "individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine."²⁷
- 25. These positive clinical results held true in the real world after the EUAs were issued. After collecting data in real world use, in April 2021, Pfizer announced that its vaccine had

²⁵ See FDA, Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum: Moderna COVID-19 Vaccine/mRNA-1273 (Dec. 18, 2020), https://www.fda.gov/media/144673/download.

²⁶ See FDA, Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum: Janssen COVID-19 vaccine (Ad26.COV2.S) (Feb. 27, 2021), https://www.fda.gov/media/146338/download.

²⁷ See FDA, Coronavirus (COVID-19) Update: FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals, (May 5, 2022),

https://www.fda.gov/media/158318/download#:~:text=Specifically%2C%20CBER%20has%20determined%20that,elect%20to%20receive%20the%20Janssen.

- 26. Initially, the COVID-19 vaccines were approved for emergency use only by adults 18 and over who are not pregnant and have healthy immune systems. After additional study, however, the FDA later extended the authorization of all three COVID-19 vaccines for pregnant women, moderately or severely immunocompromised individuals, and the Pfizer vaccine for all people 12 years of age and older. Thus, the only group for whom the Pfizer and Moderna vaccines (together, the "mRNA vaccines") are currently contraindicated are those acutely allergic to their ingredients—specifically polyethylene glycol or polysorbate—which is estimated to occur in only 2.5 to 11.1 cases per 1 million doses.³²
- 27. On August 23, 2021, the FDA approved the first vaccine—the Pfizer vaccine—for the prevention of COVID-19 disease in individuals 16 years of age and older.³³

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²⁸ See Pfizer and BioNTech Confirm High Efficacy and No Serious Safety Concerns Through Up to Six Months Following Second Dose in Updated Topline Analysis of Landmark COVID-19 Vaccine Study, Pfizer (April 1, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious.

²⁹ *Ibid*.

³⁰ See Berkeley Lovelace, Jr., Moderna says new data shows its Covid vaccine is more than 90% effective against virus six months after second shot, CNBC (April 13, 2021), https://www.cnbc.com/2021/04/13/covid-vaccine-moderna-says-new-data-shows-its-90percent-effective-six-months-after-second-dose.html.

³¹ See Kathy Katella, Comparing the COVID-19 Vaccines: How Are They Different, Yale Medicine, Aug. 26, 2021, https://www.yalemedicine.org/news/covid-19-vaccine-comparison.

³² See Kimberly G. Blumenthal et al., *Acute Allergic Reactions to mRNA COVID-19 Vaccines*, 325 JAMA 1562 (2021) https://jamanetwork.com/journals/jama/fullarticle/2777417.

³³ See Letter of Authorization, FDA (Aug. 23, 2021), https://www.fda.gov/media/144416/download.

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- 28. On January 31, 2022, the FDA announced the second approval of a COVID-19 vaccine—the Moderna COVID-19 vaccine for the prevention of COVID-19 disease in individuals 18 years of age and older.³⁴
- 29. On June 17, 2022, the FDA extended the EUAs of both mRNA vaccines to include use in children as young as six months of age.³⁵
- 30. Data also shows that COVID-19 vaccination is safe for pregnant people. Studies assessing vaccination early in pregnancy did not find an increased risk of miscarriage among pregnant people who received an mRNA COVID-19 vaccine.^{36, 37} The CDC has instead recommended that pregnant people get vaccinated against COVID-19, in part because they are at a higher risk of becoming severely ill from the disease compared to non-pregnant people.³⁸
- 31. COVID-19 vaccines continue to be the best tools available to prevent symptomatic COVID-19 and reduce the risk of persistent post-COVID symptoms/long-COVID.^{39,40} The extremely high effectiveness of the vaccines in preventing symptomatic infections was important

³⁴ See Letter of Authorization, FDA (Jan. 31, 2022), https://www.fda.gov/media/155815/download.

³⁵ See CDC Advisory Committee On Immunization Practices, Grading of Recommendations, Assessment, Development and Evaluation (GRADE): Pfizer-BioNTech COVID-19 Vaccine for Children Aged 6 Months-4 Years, https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine-6-months-4-years.html.

³⁶ See CDC, COVID-19 Vaccination for People Who Are Pregnant or Breastfeeding, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html.

³⁷ See Tom T. Shimabukuro, et al., *Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons*, 384 New England J. Med. 2273 (2021), https://www.nejm.org/doi/full/10.1056/nejmoa2104983.

³⁸ See CDC, COVID-19 Vaccines While Pregnant and Breastfeeding, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html (updated Nov. 3, 2023).

³⁹ Wu X, Xu K, Zhan P, Liu H, Zhang F, Song Y, Lv T, *Comparative efficacy and safety of COVID-19 vaccines in phase III trials: a network meta-analysis*, BMC Infect Dis. 2024 Feb 21;24(1):234. doi: 10.1186/s12879-023-08754-3. PMID: 38383356; PMCID: PMC10880292.

⁴⁰ Man MA, Rosca D, Bratosin F, Fira-Mladinescu O, Illie AC, Burtic SR, Fildan AP, Fizedean CM, Jianu AM, Negrean RA, Marc MS, Impact of Pre-Infection COVID-19 Vaccination on the Incidence and Severity of Post-COVID Syndrome: A Systematic Review and Meta-Analysis, Vaccines (Basel). 2024 Feb 12;12(2): 189. doi: 1 0.3390/vaccinesl2020189. PMID: 38400172; PMCID: PMCI 0893048.

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for slowing the spread of COVID-19, as asymptomatic cases have been found to be approximately 60% less transmissible than symptomatic cases, possibly because the lack of coughing, sneezing, and other respiratory symptoms may reduce the spread of respiratory aerosols.^{41,42}

32. As of November 2023, more than 13.5 billion COVID-19 vaccine doses had been administered around the world, and more than 5.4 billion people (67% of the global population) had received a complete primary series of a COVID-19 vaccine.⁴³ More than 270 million Americans (81.4% of the population) have received at least one COVID-19 vaccine dose, and 230 million Americans (69.5%) have completed a primary series.⁴⁴

IV. WHY VACCINES ARE SO IMPORTANT

33. In 2021 and 2022, the COVID-19 vaccines played an incredibly important role in our response to the pandemic. The vaccines were the main tool to control the pandemic and to start bringing out lives back to normal. The vaccines prevented severe illness and death, slowed the spread of new infections, reduced strain on healthcare systems, protected vulnerable populations, and allowed schools, businesses, and travel to reopen. Vaccination was the predominant

⁴¹ See Tan J, Ge Y, Martinez L, Sun J, Li C, Westbrook A, Chen E, Pan J, Li Y, Cheng W, Ling F, Chen Z, Shen Y, Huang H, *Transmission roles of symptomatic and asymptomatic COVID-19 cases: a modelling study*, Epidemiol Infect. 2022 Sep 27;150:e171. doi: 10.1017/S0950268822001467. PMID: 36263615; PMCID: PMC9588416.

⁴² See Buitrago-Garcia D, Ipekci AM, Heron L, Imeri H, Araujo-Chaveron L, Arevalo-Rodriguez I, Ciapponi A, Cevik M, Hauser A, Alam MI, Meili K, Meyerowitz EA, Prajapati N, Qiu X, Richterman A, Robles-Rodriguez WG, Thapa S, Zhelyazkov I, Salanti G, Low N, Occurrence and transmission potential of asymptomatic and presymptomatic SARS-CoV-2 infections: Update of a living systematic review and meta-analysis. PLoS Med. 2022 May 26;19(5):e1003987. doi: 10.1371/journal.pmed.1003987. PMID: 35617363; PMCID: PMC9135333.

⁴³ See World Health Org., COVID-19 vaccination, World data (Nov. 26, 2023), https://data.who.int/dashboards/covid19/vaccines.

⁴⁴ See CDC, COVID-19 Vaccinations in the United States (final update May 11, 2023), https://covid.cdc.gov/covid-data-tracker/#vaccinations vacc-people-booster-percent-pop5.

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mechanism to develop immunity in the U.S. population, followed by people with prior infections. 45,46,47

- 34. People should get vaccinated regardless of whether they already were infected with COVID-19 for several reasons. First, research has not yet shown how long a person who had COVID-19 will be protected from getting COVID-19 again after recovery. Individuals who have had COVID-19 might have some antibodies even after their infection has passed that provide protection against COVID-19. But the amount of protection that these individuals have against the virus varies from person to person and wanes over time. As these individuals' natural immunity decreases, their risk of contracting COVID-19 increases. There is no known "time threshold" after which a person's infection mediated immunity is no longer protective. As a result, unless vaccinated, they would need to get infected again, along with the entire range of potential effects (including death), to regain any level of subsequent immunity.
- 35. Second, studies show that being fully vaccinated provides better protection as compared to having recovered from COVID-19. A CDC study of individuals with previous COVID-19 infections through June 2021 found that those who were unvaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated.⁴⁹ These findings, and

⁴⁵ See Gram, M. A. et al. Vaccine effectiveness against SARS-CoV-2 infection or COVID-19 hospitalization with the Alpha, Delta, or Omicron SARS-CoV-2 variant: A nationwide Danish cohort study. *PLoS Med.* **19**, e1003992 (2022).

⁴⁶ See Lauring, A. S. et al. Clinical severity of, and effectiveness of mRNA vaccines against, covid-19 from omicron, delta, and alpha SARS-CoV-2 variants in the United States: prospective observational study. *BMJ* **376**, e069761 (2022).

⁴⁷ See Kerr, S., Vasileiou, E., Robertson, C. & Sheikh, A. COVID-19 vaccine effectiveness against symptomatic SARS-CoV-2 infection and severe COVID-19 outcomes from Delta AY.4.2: Cohort and test-negative study of 5.4 million individuals in Scotland. *J. Glob. Heal.* **12**, 05025 (2022).

⁴⁸ See COVID-19 Vaccine Frequently Asked Questions, CDC, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.

⁴⁹ See Alyson M. Cavanaugh, et al., Reduced Risk of Reinfection with SARS-CoV-2 after COVID-19—Kentucky, May-June 2021, 70 Morbidity & Mortality Weekly Report 1081 (Aug. 13, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm?s cid=mm7032e1 w.

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- 36. Other studies have found stronger immune response with vaccination after infection with COVID-19, including both higher levels of antibodies and longer duration of protection.⁵¹
- 37. The evidence also suggests that vaccines are effective at reducing the risk and severity of so-called "long COVID."⁵²
- 38. The CDC and FDA do not recommend that people use antibody or serology tests, which look for antibodies from a previous infection or from vaccination, to assess the need for vaccination in an unvaccinated person or assess immunity to SARS-CoV-2.^{53,54} This is because antibody tests have variable sensitivity and specificity, as well as positive and negative predictive values, and are not authorized for the assessment of immune response in vaccinated people. Furthermore, the serologic correlates of protection have not been established, and antibody testing does not evaluate the cellular immune response, which may also play a role in vaccine-mediated protection.

DECLARATION OF JOHN LYNCH, MD IN SUPPORT OF DEFENDANT CITY OF ISSAQUAH'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE DR. HARVEY RISCH - 16 CASE NO. 2:24-cv-01673-TL

⁵⁰ See also Leonidas Stamatatos, et al., mRNA vaccination boosts cross-variant neutralizing antibodies elicited by SARS-CoV-2 infection, 372 Science 1413 (2021), https://pubmed.ncbi.nlm.nih.gov/33766944/.

⁵¹ See Thomas W. McDade, et al., Durability of antibody response to vaccination and surrogate neutralization of emerging variants based on SARS-CoV-2 exposure history, 11 Scientific Reports 17325 (Aug. 30, 2021), https://www.nature.com/articles/s41598-021-96879-3; Alice Cho, et al., Anti- SARS-CoV-2 Reporter Binding Domain Antibody Evolution after mRNA, 600 Nature 517-522 (2021), https://www.biorxiv.org/content/10.1101/2021.07.29.454333v2.

⁵² See Greg Vanichkachorn, et al., Potential reduction of post-acute sequelae of SARS-CoV-2 symptoms via vaccination, 71 Journal of Investigative Medicine 8 (2023), https://journals.sagepub.com/doi/10.1177/10815589231191812; Oyungerel Byambasuren, et al., Effect of covid-19 vaccination on long covid: systemic review, 2 BMJ 1 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9978692/.

⁵³ See CDC, Interim Guidelines for COVID-19 Antibody Testing, https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/hcp/testing/antibody-tests-guidelines.html.

⁵⁴ See FDA, Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers, https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/antibody-serology-testing-covid-19-information-patients-and-consumer.

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- 40. Someone who would rather get infected with SARS-CoV-2 and subsequently develop COVID-19 as a means to developing some level of temporary immunity would not be making a rational choice from a public health perspective. During the emergency phase of the pandemic, that choice would have entailed substantial risks to one's own health and to the health of others.
- 41. COVID-19 infection continues to be associated with a range of outcomes including severe acute illness and death, serious, persistent symptoms due to long COVID, and other connected gastrointestinal, pulmonary, reproductive, immune, nervous, and cardiovascular system syndromes.⁵⁶
- 42. This novel virus and the diseases that it causes continue to be studied, and with our limited understanding, an intervention like vaccination that decreases infection and/or disease severity is extraordinarily important and warranted. Infected individuals also risk infecting others in their family, social community, work circles, and anyone else with whom they come in contact. Infection with COVID-19 can quickly spread to others; and each afflicted person can be a public health threat given the highly infectious nature of the virus, especially when COVID-19 was

⁵⁵ See Sudeb C. Dalai, et al., Clinical Validation of a Novel T-Cell Receptor Sequencing Assay for Identification of Recent or Prior Severe Acute Respiratory Syndrome Coronavirus 2 Infection, 75 Clinical Infectious Diseases 2079 (May 6, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9129217/.

⁵⁶ See Davis et al., Long COVID: major findings, mechanisms and recommendations, 21 Nature Reviews Microbiology 133, (Apr. 17, 2023), https://doi.org/10.1038/s41579-022-00846-2; Jin-Gyu Cheong, et al., Epigenetic memory of coronavirus infection in innate immune cells and their progenitors, 2023 Cell 186, 1-21, https://doi.org/10.1016/j.cell.2023.07.019.

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- 43. All these issues outweigh any infection-mediated immunity benefits. Vaccines are safe, effective, and associated with mild side effects and a greatly reduced risk of severe illness or death.
- 44. Alternatives to vaccination, such as regular COVID-19 testing, would not have been an adequate public health strategy to defeat COVID-19. Unvaccinated people, subject to regular testing, are among positive cases that have caused outbreaks in Washington State. For example, past opt-out testing policies for unvaccinated staff in congregate facilities have not been effective at preventing new COVID-19 infections—adversely affecting employees, clients, and families, and even the lives of dedicated staff. Workplace outbreaks in 2021 were also common.⁵⁹
- 45. In addition, tests are not 100% accurate. There are 2 types of tests: polymerase chain reaction ("PCR") tests and antigen tests. PCR testing must be administered by a healthcare worker, which most non-healthcare employers would have to hire to obtain the specimens. While getting a PCR test at a dedicated testing facility is possible, doing so would require additional time away from work, and reliance on the delivery of results by the employee to the employer in a timely fashion. Both factors lead to more delay between the swab being obtained and the receipt of

⁵⁷ See Liu Y; Centre for Mathematical Modelling of Infectious Diseases nCoV Working Group; Funk S, Flasche S. The contribution of pre-symptomatic infection to the transmission dynamics of COVID-2019. Wellcome Open Res. 2020 Apr 1;5:58. doi: 10.12688/wellcomeopenres.15788.1. PMID: 32685697; PMCID: PMC7324944; Song Y, Shim E. Proportion of Pre-Symptomatic Transmission Events Associated with COVID-19 in South Korea. J Clin Med. 2022 Jul 6;11(14):3925. doi: 10.3390/jcm11143925. PMID: 35887689; PMCID: PMC9324033.

⁵⁸ See Shi N, Huang J, Ai J, Wang Q, Cui T, Yang L, Ji H, Bao C, Jin H. Transmissibility and pathogenicity of the severe acute respiratory syndrome coronavirus 2: A systematic review and meta-analysis of secondary attack rate and asymptomatic infection. J Infect Public Health. 2022 Mar;15(3):297-306. doi: 10.1016/j.jiph.2022.01.015. Epub 2022 Jan 31. PMID: 35123279; PMCID: PMC8801962.

⁵⁹ Sara Luckhaupt, et al., *COVID-19 Outbreaks Linked to Workplaces*, 23 US Jurisdictions, August-October 2021, 138 Public Health Report 333 (2023), https://pubmed.ncbi.nlm.nih.gov/36482712/.

a potentially positive test result, and more time for exposing more coworkers and members of the public to COVID-19. Accordingly, regular PCR tests would likely require an infrastructure for supplying swabs and transport media, transportation of the specimens to a contracted lab, and a mechanism for the lab results to be communicated back to the employer. There would also need to be a tracking database, and a person assigned to tracking the tests, test cadence, and test results. A person with knowledge of medical testing result interpretation would need to be available to provide recommendations based on the test results, which are often ambiguous. With ambiguous results, the worker may be required to remain at home in isolation when not infected. For most employers outside of healthcare, this would be a complex and likely costly process that, in 2021 and 2022, would need to be maintained indefinitely as the direction of the pandemic was very much unknown.

- 46. PCR tests can take a day or more to return results. The sensitivity of this test is very good but can remain positive for weeks after resolution of infection, during which time a person could be re-infected, and the new infection would not be detected. Accordingly, regular PCR testing may fail to detect a COVID-19 infection. In addition, individuals can be infected with and transmit COVID-19 while they are either asymptomatic or in a pre-symptomatic phase. This means that a person, while waiting for her test result, would be working with others, and potentially transmitting COVID-19.
- 47. The alternative approach is to use "rapid" antigen tests. While antigen testing could be done by the employee, antigen tests were not commonly available at the time of the initial vaccine mandate and were also not widely available at the time of the Plaintiff's accommodation requests. In addition, they were not FDA approved for testing asymptomatic people. This is due to the poor sensitivity of an antigen test even for symptomatic individuals. A test with poor sensitivity means that a person could have a negative test while they are in fact infected, allowing them to work and to transmit COVID-19. Such a false negative test may also encourage behaviors

- 48. For example, in a study reviewing publications through March 2021 concluded that even for indicated use (a symptomatic person), the rapid (antigen) tests fail to positively detect infection approximately 20% to 30% of the time with the first week of symptom onset. For asymptomatic individuals, sensitivity of the rapid (antigen) tests (the ability to detect infection when infection is present) ranges from 35.8% to 71%. In a review of studies of rapid (antigen) tests used for this purpose, researchers found that roughly half of those identified by PCR tests as infected had a negative rapid (antigen) test. The conclusion of the study authors was as follows: "The results of this rapid review indicate serious issues in misidentifying asymptomatic individuals as COVID-19 negative, when in fact they are infected and carrying the SARS-CoV-2 virus."
- 49. It is also possible for a worker to test negative on a given day, contract COVID-19 the next day, and be contagious before the next test occurs. In the meantime, that unvaccinated individual could have potentially exposed their families, colleagues, or other persons with whom they come into contact to COVID-19. The turn-around time from obtaining a test swab to having an actionable result also varies. For the more accurate PCR tests, result times vary from, at a minimum 6 to 8 hours, to days. During this time, infected employees would be exposing all those around them. Rapid antigen tests allow for faster results but have a significantly higher rate of

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⁶⁰ See Dinnes, J., et al., Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection, 7 Cochrane Database of Systemic Reviews 2022,

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013705.pub3/full (originally published August 26, 2020 and updated March 24, 2021, and July 22, 2022).

⁶¹ See Alyssa M. Indelicato, et al., Rapid Antigen Test Sensitivity for Asymptomatic COVID-19 Screening, 6 PRiMER 18 (2022),

 $[\]frac{https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9258726/\#:\sim:text=Sensitivity\%20ranged\%20from\%2035.8\%25\%20too,the\%20higher\%20number\%20about\%20exposur.$

⁶² Ibid.

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- 50. Because PCR tests can take multiple days to return results, even if the Plaintiff submitted to PCR tests every day, that would not avoid the risk that they would be infected with and/or transmit COVID-19 while at work. And because of the risks of false negative PCR tests and asymptomatic infection and transmission, a regimen of daily PCR testing would similarly not avoid those risks.
- 51. Further, at various points during the emergency phase of the pandemic there were shortages of rapid antigen tests, including in fall 2021, which would create serious issues for protocols that are over-reliant on testing to prevent infected individuals from spreading the virus.⁶⁴
- 52. Additionally, the benefits of some equipment thought of as protective are not supported by research findings. For example, plastic barriers or shields were frequently deployed during the pandemic as a "common-sense" intervention to prevent transmission when physical distancing was not possible. The basis for the use of these physical barriers was to block the flow of infectious droplets from the infected person to the uninfected person on the other side of the barrier. Critically, there were no real data to support the use of these tools, especially after it was established that the primary mode of COVID-19 transmission was aerosol-based and not droplets. Aerosols, as floating "clouds" of invisible particles can easily move around, including around barriers and through any openings in the barriers. In a study by Cadnum, *et al.*, it was

⁶³ See CDC, COVID-19 Testing: What You Need to Know, Sept. 25, 2023, https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html.

⁶⁴ See CDC, Lab Advisory: Shortage of COVID-19 Rapid Tests May Increase Demand for Laboratory Testing, Sept. 2, 2021, https://www.cdc.gov/locs/2021/09-02-2021-lab-advisory-Shortage_COVID-19 Rapid Tests Increase Demand Laboratory Testing 1.html.

⁶⁵ See JC Chamary, Why Face Shields and Plexiglass Barriers Don't Block Coronavirus, Forbes, Oct 23, 2020, https://www.forbes.com/sites/jvchamary/2020/10/23/covid19-coronavirus-aerosols/?sh=5c3f82bc1541.

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shown that barriers with any openings were ineffective.⁶⁶ The same research group published another study highlighting that barriers can increase the risk of transmission to the person behind the barrier.⁶⁷ Air is brought into and removed from built environments based on the known structure of that environment and plastic barriers interfere with mechanical ventilation and airflow and can increase the concentration of infectious aerosols on the "protected" side of the barrier.^{68, 69} Notably, the CDC does not include the use of plastic barriers as a tool to reduce the risk of COVID-19.⁷⁰ Protective equipment like these plastic barriers are not effective tools for mitigation, especially when compared to vaccination programs.

53. Likewise, use of personal protective equipment is a complement—not a substitute—for getting vaccinated. Masks and vaccines share the goal of preventing infection, disease, and virus transmission, and they accomplish it in complementary ways. Masks shore up protection on the outside (when worn and worn properly); vaccines shore up security through immunity from the inside. Moreover, a work-based masking requirement applies only while employees are at work. Those employees may become infected while outside of work, for example at home where one would not be expected to wear a mask. Vaccines, on the other hand, are effective around the clock. There is no combination of mitigations for individuals who are going to work onsite that are equivalent to those same mitigations, or a subset of those mitigations, in

⁶⁶ Cadnum JL, et al., *Do plexiglass barriers reduce the risk for transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)?*, 44 Infection Control & Hospital Epidemiology 2023, 1010-13, https://pubmed.ncbi.nlm.nih.gov/34726150/ (e-published in Nov. 2021).

⁶⁷ Cadnum JL,et al., *Real-World Evidence on the Effectiveness of Plexiglass Barriers in Reducing Aerosol Exposure*. 4 Pathogens & Immunity 2022, 66-77, https://pubmed.ncbi.nlm.nih.gov/36381131/.

⁶⁸ See Tara Paker-Pope, *Those Anti-Covid Plastic Barriers Probably Don't Help and May Make Things Worse*, N.Y. Times, Aug. 19, 2021, https://www.nytimes.com/2021/08/19/well/live/coronavirus-restaurants-classrooms-salons.html.

⁶⁹ See Vuorinen V, et al., Modelling aerosol transport and virus exposure with numerical simulations in relation to SARS-CoV-2 transmission by inhalation indoors, 130 Saf Sci. 2020, https://pubmed.ncbi.nlm.nih.gov/32834511/.

⁷⁰ See Ventilation in Building, CDC, https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html (updated May 12, 2023).

- 54. The cited studies in **Exhibits B & C**, as well as data and recommendations from national, state, and local public health officials, strongly support the conclusion that vaccination combined with non-pharmaceutical interventions (NPIs) like sick leave, masking, social distancing, and testing, was superior to using NPIs alone. There are no studies demonstrating that NPIs alone were or are equivalent to NPIs plus vaccination to reduce the risk of infection and transmission in the workplace. Attached hereto as **Exhibit D** are two illustrative documents that demonstrate the hierarchy of potential methods for preventing infection and virus transmission.
- 55. Researchers from the Yale School of Public Health estimated by the end of June 30, 2021, COVID-19 vaccines prevented nearly 280,000 deaths and 1.25 million hospitalizations in the United States.⁷¹
- 56. By December 2021, those estimates increased to vaccines preventing over 1 million deaths and 10 million hospitalizations in the United States.⁷² The majority of these prevented deaths and hospitalizations would have occurred in the late summer and fall of 2021.⁷³
- 57. At the end of 2022, those estimated numbers increased yet again. Researchers now estimate COVID-19 vaccines in the U.S. prevented over 3 million deaths and 18 million hospitalizations.⁷⁴ In a more recent study evaluating the impact of COVID-19 vaccines in select Latin American and Caribbean countries, researchers estimated that between 610,000 and

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⁷¹ See Alison Galvani, et al., Deaths and Hospitalizations Averted by Rapid U.S. Vaccination Rollout, The Commonwealth Fund, Jul. 7, 2021, https://www.commonwealthfund.org/publications/issue-briefs/2021/jul/deaths-and-hospitalizations-averted-rapid-us-vaccination-rollout.

⁷² See Eric Schneider, et al., *The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted*, The Commonwealth Fund, Dec, 14, 2021, https://www.commonwealthfund.org/publications/issue-briefs/2021/dec/us-covid-19-vaccination-program-one-year-how-many-deaths-and.

⁷³ *Ibid*.

⁷⁴ See Megan Fitzpatrick, et al., Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths, The Commonwealth Fund, December 13, 2022,

https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations.

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2,610,000 deaths were prevented due to vaccination.⁷⁵ It has clearly been shown throughout all phases of the pandemic that COVID-19 vaccines are safe and reduce infection rates, transmission, disease severity, long COVID, and death due to COVID-19.

V. 2021 WASHINGTON STATE VACCINE REQUIREMENTS AND POST-VACCINE VARIANTS

- 58. In the late summer and early fall of 2021, Governor Inslee issued several iterations of Proclamation 21-14 ("State Proclamation"), which collectively prohibited most state employees and Washington healthcare providers from working after October 18, 2021, without being fully vaccinated against COVID-19.⁷⁶ When it took effect, the State Proclamation applied to three covered sectors—state government, healthcare, and education.
- 59. On August 10, 2021, the King County Executive issued Executive Order ACO-8-27-EO (the "Executive Order"), which prohibited King County executive branch employees from working after October 18, 2021, without being fully vaccinated against COVID-19.⁷⁷
- 60. I understand that on August 20, 2021, City of Issaquah Mayor Mary Lou Pauly and City Administrator Wally Bobkiewicz issued an Update: COVID-19 (Coronavirus) Protection Plan & Policy Updates August 10 and 20, 2021, which required City of Issaquah employees to be fully vaccinated against COVID-19 as a condition of employment by October 18, 2021. I also understand that the City's vaccination policy provided that workers who were medically unable or had an objection to the vaccine based upon a sincerely held religious belief could apply for an exemption and accommodation from the vaccination requirement.

⁷⁵ See Alexandra Savinkina, Daniel M Weinberger, Cristiana M Toscano, Lucia H De Oliveira, Estimated deaths averted in adults by COVID-19 vaccination in select Latin American and Caribbean Countries, *Open Forum Infectious Diseases*, 2024, https://doi.org/10.1093/ofid/ofae528.

⁷⁶ See Office of Washington Governor Jay Inslee, *Proclamations*, Procl. 21-14.1 at 4, Aug. 20, 2021, https://governor.wa.gov/sites/default/files/proclamations/21-14.1%20-%20COVID-19%20Vax%20Washington%20Amendment.pdf.

⁷⁷ King County Executive, Order Pursuant to Proclamation of Emergency; COVID-19 Vaccination Requirements for Executive Branch Employees, Aug. 10, 2021, https://your.kingcounty.gov/dnrp/temp/ACO-8-27-EO-emergency-order-covid-19-vaccination-requirements.pdf

approached levels last seen in the winter 2020 COVID-19 surge. As of July 30, the DOH said 1 in 172 Washington residents was estimated to have an active COVID-19 infection. Ry August 6, 1 in 156 Washington residents was estimated to have an active COVID-19 infection. Ry August 6, 1 in 156 Washington residents was estimated to have an active COVID-19 infection. Ry The increase in COVID-19 infections put a strain on hospitals already dealing with staffing challenges, which was compounded by an increase in staff who have tested positive for the virus. Hospitalizations in the state due to COVID-19 were at an all-time high in late August of 2021. At the time, unvaccinated individuals between the ages of 16 and 64 were 10 times more likely to be hospitalized than those who were vaccinated. In September of 2021, 95% of hospitalized patients were unvaccinated. In the period leading up to December 2021, in King County unvaccinated persons were 4.5x more likely to test positive for COVID-19 than fully vaccinated persons, 32x more likely to be hospitalized, and 40x more likely to die. Attached as Exhibit F is a true and correct copy of Seattle and King County Public Health COVID-19 Outcomes by Vaccination

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⁷⁸ King 5, *Delta variant causing COVID-19 cases to spread 'like wildfire' in Washington*, Aug. 15, 2021, https://www.king5.com/article/news/health/coronavirus/delta-variant-covid-19-infections-spreading-washingtonstate/281-4bace20b-469e-4e00-8dbe-ce15c5cf32e6.

⁷⁹ Rich Mendez, *Washington state Covid transmission and hospitalizations hit all-time high*, CNBC, Aug. 20, 2021, https://www.cnbc.com/2021/08/20/covid-washington-state-infections-and-hospitalizations-hit-record.html.

⁸⁰ *Ibid*.

⁸¹ *Ibid*.

⁸² See Kate Walter, Washington state Covid-19 hospitalizations still at 'sobering' levels, KUOW, Sep. 13, 2021, https://www.kuow.org/stories/washington-state-covid-19-hospitalizations-still-at-sobering-levels.

- 63. Data suggested the Delta variant caused more severe illness than previous variants in unvaccinated people. In studies conducted in Scotland and Canada, patients infected with the Delta variant were more likely to be hospitalized than patients infected with other strains of the virus.⁸³ The data also suggested that the Delta variant was more infectious and that unvaccinated individuals were likely to be infectious for longer than vaccinated individuals.⁸⁴
- 64. At the time the Proclamation and City's Order requiring vaccination were announced, data also suggested that vaccination offered higher protection than previous COVID-19 infection. In a CDC study spanning from January to September of 2021, participants were over five times more likely to have COVID-19 again if they were unvaccinated and had a prior infection. A separate September 2021 CDC report found that unvaccinated people were five times more likely to contract, ten times more likely to be hospitalized with, and eleven times more likely to die from COVID-19 than those who were fully vaccinated. And, as the CDC stated in August 2021, "[t]he Delta variant causes more infections and spreads faster than earlier forms of

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⁸³ See CDC, Delta Variant: What We Know About the Science, August 6, 2021, https://stacks.cdc.gov/view/cdc/108671.

⁸⁴ *Ibid*.

⁸⁵ See CDC, Vaccination Offers Higher Protection then Previous COVID-19 Infection, Oct. 29, 2021, https://www.cdc.gov/#/details?url=https://www.cdc.gov/media/releases/2021/s1029-Vaccination-Offers-Higher-Protection.html.

⁸⁶ See Catherine H. Bozio, et al., Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19-Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity – Nine States, January-September 2021, 70 Morbidity & Mortality Weekly Report 1539 (2021), https://www.cdc.gov/mmwr/volumes/70//wr/mm7044e1.htm.

⁸⁷ See CDC, Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status — 13 U.S. Jurisdictions, April 4–July 17, 2021, 70 Morbidity & Mortality Weekly Report 1539 (2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm?s_cid=mm7037e1_w.

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the virus that causes COVID-19," but "[v]accines continue to reduce a person's risk of contracting the virus that causes COVID-19, including this variant."88

65. The Delta variant was followed by the Omicron waves. On November 25, 2021, scientists in South Africa identified a new variant, which would later be named Omicron. ⁸⁹ Less than a month after its discovery in South Africa, Omicron was the dominant strain of the virus in the United States. ^{90, 91} The highly infectious Omicron variant waves began in late 2021, displacing the Delta variant in the United States. Subvariants in the same Omicron family continue to constitute all COVID-19 waves to this day. ⁹² Within weeks of the first detected case of COVID-19 due to the Omicron variant in December 2021, cases, hospitalizations, and deaths due to COVID-19 in the United States and in Washington State started to climb quickly as this variant spread. ⁹³ By the middle of January 2022 in Washington, COVID-19 cases reached record levels with case counts (positive tests) of 1750.3 per 100,000 (137,649 cases during the week of 1/9/22-1/15/22), almost 20% of all hospitalizations due to COVID-19 infection, and 4.1 deaths per 100,000 (322 deaths the week of 1/23/22-1/29/22). ⁹⁴ During this period of high transmission, COVID-19

⁸⁸ See CDC, Benefits of Getting a COVID-19 Vaccine, Aug. 16, 2021, https://web.archive.org/web/20211018080349/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html (web archive from Oct. 18, 2021).

⁸⁹ See South Africa detects new variant, prompting new international travel restrictions, N.Y. Times, Nov. 26, 2021, https://www.nytimes.com/2021/11/25/world/variant-south-africa-covid.html.

⁹⁰ See Travis Caldwell and Clair Colbert, *Omicron is now the dominant strain of coronavirus in the U.S. according to the CDC*, CNN, Dec. 21, 2021, https://www.cnn.com/2021/12/20/health/us-coronavirus-monday/index.html.

⁹¹ See Omicron now dominant virus strain in King County, Western WA, Associated Press, Dec. 21, 2023, https://apnews.com/article/coronavirus-pandemic-health-seattle-washington-e3e6671b7e863d51700e0e03bcfd70d2 ("[T]he super-infectious variant will soon overtake delta throughout the rest of the state.").

⁹² See CDC, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#variant-proportions.

⁹³ See CDC, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_select_00; Wash. DOH, Respiratory Illness Data Dashboard, https://doh.wa.gov/data-and-statistical-reports/diseases-and-chronic-conditions/communicable-disease-surveillance-data/respiratory-illness-data-dashboard

⁹⁴ See Wash. DOH, Respiratory Illness Data Dashboard, https://doh.wa.gov/data-and-statistical-reports/diseases-and-chronic-conditions/communicable-disease-surveillance-data/respiratory-illness-data-dashboard

vaccination continued to provide protection from infection, hospitalization, and death due to COVID-19.95

- 66. Though breakthrough infections increased with the Omicron variant, the vaccines, particularly with booster doses, remained highly effective in preventing severe illness caused by Omicron. For example, the World Health Organization held a virtual meeting on March 15, 2022, to review evidence from several studies that assessed COVID-19 vaccine effectiveness against severe Omicron disease using several outcome definitions. After reviewing those studies, the researchers concluded that "current vaccine formulations continue to have utility in preventing the most severe forms of diseases." Multiple other studies have found similar results. 97
- 67. It is important to remember that much of what we know now about the virus and the disease was unknown at the time the City's Order, King County Executive Order, and State Proclamation requiring vaccination were announced. In 2021, it was unknown exactly how the virus was transmitted and what mitigations, aside from vaccination, were the most effective. As new variants emerged with greater transmission potential and greater pathogenicity, they reshaped our understanding of transmission protection.

DECLARATION OF JOHN LYNCH, MD IN SUPPORT OF DEFENDANT CITY OF ISSAQUAH'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE DR. HARVEY RISCH - 28 CASE NO. 2:24-cv-01673-TL

(2022), https://www.nature.com/articles/s41591-022-01753-y.

⁹⁵ See CDC, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness, DOI: http://dx.doi.org/10.15585/mmwr.mm7142a3; DOI: http://dx.doi.org/10.15585/mmwr.mm7142a4; Emma K. Accorsi, et al., http://creativeness of Homologous and Heterologous Covid-19 Boosters against Omicron, 386 N. Engl. J. Med. 2433(2022), https://www.nejm.org/doi/10.1056/NEJMc2203165.

⁹⁶ See Daniel R. Feikin, et al., Assessing vaccine effectiveness against severe COVID-19 disease caused by omicron variant. Report from a meeting of the World Health Organization, 40 Vaccine 3516 (2022), https://www.sciencedirect.com/science/article/pii/S0264410X22005230?via%3Dihub.

⁹⁷ See also Mie Agermose Gram, et al., Vaccine effectiveness against SARS-CoV-2 infection or COVID-19 hospitalization with the Alpha, Delta, or Omicron SARS-CoV-2 variant: A nationwide Danish cohort study, Plos Medicine, Sept. 1, 2022, https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003992; Adam S. Lauring, et al, Clinical severity of, and effectiveness of mRNA vaccines against, covid-19 from omicron, delta, and alpha SARS-CoV-2 variants in the United States: prospective observational study, BMJ, Mar. 9, 2022, https://www.bmj.com/content/376/bmj-2021-069761; Mark G. Thompson, et al., Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19—Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance, 71 Morbidity & Mortality Weekly Report 139 (2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e3.htm; Hung Fu Tseng, et al., Effectiveness of mRNA-1273 against SARS-CoV-2 Omicron and Delta variants, 28 Nature Medicine 1063

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69. Aerosol transmission implied that infections could occur over greater distances than previously thought, including via ventilation ducts, and in spaces that were previously inhabited by individuals with COVID-19. This mechanism explained cases and outbreaks of transmission spread over distance and over time versus direct, near contact. Outbreaks were described in outdoor café settings and in vertically oriented apartments separated by floors and

⁹⁸ See Julian W. Tang, et al., Airborne transmission of respiratory viruses including severe acute respiratory syndrome coronavirus 2, 29(3) Current Opinion Pulmonary Medicine 191, .https://pubmed.ncbi.nlm.nih.gov/36866737/.

⁹⁹ See Noorimotlagh Z, Jaafarzadeh N, Martínez SS, Mirzaee SA. A systematic review of possible airborne transmission of the COVID-19 virus (SARS-CoV-2) in the indoor air environment. Environ Res. 2021 Feb;193:110612. doi: 10.1016/j.envres.2020.110612. Epub 2020 Dec 10. PMID: 33309820; PMCID: PMC7726526.

¹⁰⁰ See Tai, D. B. G., Sia, I. G., Doubeni, C. A. & Wieland, M, Disproportionate Impact of COVID-19 on Racial and Ethnic Minority Groups in the United States: a 2021 Update, Journal of Racial and Ethnic Health Disparities 9, 2334–2339 (2022).

¹⁰¹ See Acosta, A. M. et al., Racial and Ethnic Disparities in Rates of COVID-19–Associated Hospitalization, Intensive Care Unit Admission, and In-Hospital Death in the United States From March 2020 to February 2021, JAMA Netw. Open 4, e2130479 (2021).

¹⁰² See Khanijahani, A., Iezadi, S., Gholipour, K., Azami-Aghdash, S. & Naghibi, D, A systematic review of racial/ethnic and socioeconomic disparities in COVID-19, Int. J. Equity Heal. 20, 248 (2021).

doors but connected by ventilation ducts.¹⁰³ Based on available data at the time the City's Order, King County Executive Order, and State Proclamation requiring vaccination were announced, work in large spaces or even outdoors was not clearly associated with a decreased risk of infection.¹⁰⁴ Even jobs requiring a significant amount of time spent outdoors could bring employees into proximity with others. As examples, police officers have some of the highest recorded times spent outdoors, but also have some of the highest risks of COVID exposure and infection and COVID-19 was the leading cause of police officer deaths in 2020, 2021, and 2022.¹⁰⁵ Similarly, there was a well-documented COVID-19 outbreak among wildland firefighters in 2020.¹⁰⁶

70. In the original epidemiological descriptions of COVID-19 outbreaks, construction workers working in outdoor settings were included among those who were infected. Subsequent studies have described outdoor outbreaks linked to joggers, campers, and outdoor market

DECLARATION OF JOHN LYNCH, MD IN SUPPORT OF DEFENDANT CITY OF ISSAQUAH'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE DR. HARVEY RISCH - 30 CASE NO. 2:24-cv-01673-TL

¹⁰³ See Pengcheng Zhao, Analysis of COVID-19 clusters involving vertical transmission in residential buildings in Hong Kong, 16(5) Build Simul. Building Simulation 701, (August 31, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9430008.

¹⁰⁴ See Elizabeth L. Yanik, et al., Occupational characteristics associated with SARS-CoV-2 infection in the UK Biobank during August–November 2020: a cohort study, 22(1) BMC Public Health 1884 (Oct. 10, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9549452/.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9549452/.

¹⁰⁵ See Department of Justice, Line of Duty Deaths Due to COVID-19, https://cops.usdoj.gov/ric/Publications/cops-w0902-pub.pdf; Officers Down Memorial Page, Honoring Officers Killed in 2021, https://www.odmp.org/search/year?year=2021; Nat'l Law Enforcement Officers Memorial Fund, 2022 End-of-Year https://nleomf.org/wp-content/uploads/2023/01/2022-EOY-Fatality-Rept-FINAL-opt.pdf (last visited Feb. 16, 2024).

¹⁰⁶ See Amanda Reiff Metz, et al., Investigation of COVID-19 Outbreak among Wildland Firefighters during Wildfire Response, Colorado, USA, 2020, 28 Emerging Infectious Diseases 8 (Aug. 1551 (2022), https://wwwnc.cdc.gov/eid/article/28/8/22-0310 article.

¹⁰⁷ See Ministry of Health Singapore Press Releases, February 14, 2020, https://www.moh.gov.sg/newshighlights/details/two-more-cases-discharged-nine-new-cases-of-covid-19-infection-confirmed; David Koh, *Occupational risks for COVID-19 infection*, 70 Occupational Medicine 1 (February 28, 2020); https://academic.oup.com/occmed/article/70/1/3/5763894?login=true.

¹⁰⁸ Li Qi, *An Outbreak of SARS-CoV-2 Omicron Subvariant BA.2.76 in an Outdoor Park - Chongqing Municipality, China*, August 2022, PubMed (Nov. 18, 2022) https://pubmed.ncbi.nlm.nih.gov/36483192/.

¹⁰⁹ Na-Young Kim, et al., *The first outbreak of coronavirus disease (COVID-19) at outdoor camping site in South Korea*, 2020, 34 J. of Epidemiology (2024) https://pubmed.ncbi.nlm.nih.gov/37460295/.

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- 71. Though some of our knowledge has evolved, what we did know in 2021 and 2022 (and what is still true) is that vaccines offer protection against transmission—both indoors and outdoors—and that reducing transmission limits the development of more dangerous variants, eases pressure on extremely overwhelmed health care facilities and saves lives.
- 72. Based on recommendations from the CDC, the Washington Department of Health, local health jurisdictions, and my own research and understanding, it is my opinion that vaccination was and is the single best tool available for stemming the spread of COVID-19 and its variants, especially when used in combination with other mitigations. Vaccination against COVID-19 is fast (each dose takes about 20 seconds to administer), extremely safe, and highly effective at preventing transmission of the virus and especially severe disease and death. It remains the most important and effective public health tool at our disposal to combat COVID-19. No other public health strategy could effectively meet the City's goals of maintaining critical governmental services and operations while protecting the health, safety, and well-being of City employees and the public at large.

VI. VACCINE MISINFORMATION AND MISCONCEPTIONS

73. Throughout the emergency phase of the pandemic and through today, people have been exposed to a great deal of information from a variety of sources, including news, public health guidance, fact sheets, infographics, and research, as well as opinions, rumors, myths, and outright falsehoods. The World Health Organization and the United Nations have characterized this unprecedented spread of information as an "infodemic." 111

¹¹⁰ Mingyu Luo, et al., *Analysis of a super-transmission of SARS-CoV-2 omicron variant BA.5.2 in the outdoor night market*, 4 Frontiers in Public Health (July 4, 2023), https://pubmed.ncbi.nlm.nih.gov/37469696/.

¹¹¹ See World Health Organization, United Nations, et al., Managing the COVID-19 infodemic: Promoting healthy behaviors and mitigating the harm from misinformation and disinformation, Sep. 23, 2020,

12 Community" that focused on preventing the spread of misinformation and providing factual 13 statistics and resources about the COVID-19 vaccines. DOH has also collected resources and 14

prepared outreach strategies for communities that may be disproportionately impacted by

COVID-19.114

76. Because vaccinated persons can become infected, that has led some people to mistakenly believe that there is no difference between vaccinated and unvaccinated persons in terms of their viral loads and/or infection rates. Experts in immunology and in vaccine development agree that there are no "perfectly" effective vaccines, just like there are no perfectly

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¹¹² See, e.g., Krista Konger, How misinformation, medical mistrust fuel vaccine hesitancy, Stanford Medicine, Sep.

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2, 2021, https://med.stanford.edu/news/all-news/2021/09/infodemic-covid-19.html.

https://www.who.int/news/item/23-09-2020-managing-the-covid-19-infodemic-promoting-healthy-behaviours-andmitigating-the-harm-from-misinformation-and-disinformation.

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¹¹³ See Adela Suliman, Most unvaccinated Americans believe coronavirus vaccine poses greater health risk than the disease, poll finds, Wash. Post., Aug. 4, 2021, https://www.washingtonpost.com/nation/2021/08/04/kff-pollcoronavirus-vaccine-unvaccinated-americans/.

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¹¹⁴ See DOH, COVID-19 Vaccine - Equity and Engagement, https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/Engagement#heading758.

effective other medications. ^{115, 116} There are multiple studies from 2021 that investigated this issue with the COVID vaccines. For example, in a paper published in JAMA in May 2021 that tracked both symptomatic and asymptomatic healthcare workers ("HCW") in Israel, the rate of symptomatic infection in vaccinated HCW was 4.7 per 100,000 person-days and 149.8 per 100,000 in the unvaccinated cohort. ¹¹⁷ The asymptomatic infection rate in the vaccinated group was 19.1 per 100,000 person-days and in the unvaccinated group it was 67.9 per 100,000 person-days. ¹¹⁸ These findings were replicated in multiple other studies supporting reduction of infection and transmission following vaccination. ^{119, 120} Importantly, the choice to remain unvaccinated impacts not only the health of the person making this decision, but having more unvaccinated people in the population also increases the risk of infection for all people, vaccinated and unvaccinated. ¹²¹

77. Even if the (unsupported) assertion that viral loads are similar is correct, the rate of both asymptomatic and symptomatic infection in the vaccinated population is statistically and dramatically lower. As a result, both the vaccinated person and all of those around them are at much lower risk of infection. Dismissing the benefits of vaccination by stating that some

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¹¹⁵ See Robert Lea, Fact Check: Is it Rare for Any Vaccine to Stop All Transmission, Infection? Newsweek, Oct. 15, 2021, https://www.newsweek.com/fact-check-rare-vaccine-stop-all-transmission-infection-1638518.

¹¹⁶ See CDC, Explaining How Vaccines Work, May 24, 2023, https://www.cdc.gov/vaccines/hcp/conversations/understanding-vacc-work.html.

¹¹⁷ See Yoel Angel, et al., Association Between Vaccination with BNT162b2 and Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infections Among Healthcare Workers, 325 JAMA 2457 (2021), https://pubmed.ncbi.nlm.nih.gov/33956048/.

¹¹⁸ *Ihid*.

¹¹⁹ See Ottavia Prunas, et al., Vaccination with BNT162b2 reduces transmission of SARS-CoV-2 to household contacts in Israel, 375 Science 375 1151 (2022), https://pubmed.ncbi.nlm.nih.gov/35084937/.

¹²⁰ See S.T. Tan, et al., Infectiousness of SARS-CoV-2 breakthrough infections and reinfections during the Omicron wave, 29 Nature Medicine 358 (2023), https://www.nature.com/articles/s41591-022-02138-x.

¹²¹ See Fisman DN, et al., Impact of population mixing between vaccinated and unvaccinated subpopulations on infectious disease dynamics: implications for SARS-CoV-2 transmission. 194 Canadian Medical Association Journal 573 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9054088/.

¹²² *Ibid*.

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- 78. In the context of a police officer, being vaccinated reduces the risk of both symptomatic and asymptomatic infection, thus reducing the police officer's risk of infection and the risk of transmission from that person to others. Of note, later studies have found not only a reduced risk of infection and reduced severity of symptoms once infected, but also lower viral loads for both the Delta and Omicron variants (in 2022) among vaccinated frontline and essential workers following vaccination compared to unvaccinated individuals.¹²³
- 79. Dixson states that as of November 2023, she "did not contract CV19 and still have not." She also said she never tested positive when subject to testing by the City in late 2021 and early 2022. If this is correct, she was at the highest risk of infection at the time of the City's Order (compared to those who were vaccinated or had a recent infection). Dixson cannot be sure she never had COVID-19 unless she has the results of antibody tests, also known as serology tests, that can confirm a past COVID-19 infection; and even that may not be accurate depending on when the test was taken. Dixson may have been infected and asymptomatic in the past and may be in the future. She may have also had respiratory symptoms and decided not to get tested. To the extent that she is basing this assertion on the results of a rapid test, which appears to be what she is describing, such tests are not 100% accurate, as described above.
- 80. Dixson has also stated that she has "God given natural immunity," which she thinks will protect her from COVID-19. From an immunological perspective, the only way to have a COVID-specific immune response (T-cell or B-cell/antibody response) is to be exposed to the

Telephone: (206) 676-7000 Fax: (206) 676-7001

¹²³ See Mark G. Thompson, et al., Association of mRNA Vaccination with Clinical and Virological Features of COVID-19, 328 JAMA 1523 (2022), https://jamanetwork.com/journals/jama/fullarticle/2797418.

pathogen or parts of the pathogen (antigens). In the case of COVID-19, this means either being infected with the virus that causes COVID-19, SARS-CoV-2 or being vaccinated. The term "natural" has no biological meaning as the immunological response is entirely human derived regardless of the source of exposure (infection or vaccination). More accurate terms are derived from the source of exposure. For example, "post-infection" and "vaccine-derived" immune responses. As humans we are not born with virus specific immune responses due to incomplete maturation of the neonatal immune system, hence the higher risk of infection in that population. Once the immune system matures, all subsequent pathogen-specific immunity is the result of exposure by infection or vaccination. It is important to recognize that unlike the immune response generated by vaccination, the development of a pathogens-specific response following infection requires that the person survives the infection and takes the risk of symptomatic infections ranging from asymptomatic to severe (requiring intensive care support), long COVID, and transmission to those around them.

I understand to mean that she is asserting that she never transmitted COVID to either co-workers or the public. There are no processes that carry a 100% rate of safety from infection aside from more radical practices like staying in one's home, alone, and not leaving or interacting with another person. If a person leaves their home or lives with other people, they are taking some risk of infection and transmission to others. For example, a person could wear a fit-tested respirator when they leave their home, but if anyone in their home does not do the same, the person would be at-risk at home (unless they always wore a fit-tested respirator at home). Infections are more commonly transmitted in indoor public and crowded settings, but they can also occur outdoors due to the physics of aerosol transmission. A person who has the goal of maximizing their protection from COVID-19 would not eat at restaurants, drink anything in a public indoor setting, eat anything at a friend's or relative's home, or find any occasion to remove their respirator when around another person or people. Relevant to her statement that she was 100% safe is the implicit

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assumption that Dixson was never infected and never transmitted to anyone else. Questions that would need to be answered to support that claim include: (a) how were these facts established; (b) how frequently did she undergo PCR testing to confirm that she did not have an asymptomatic infection; (c) how often were the individuals she was working with or otherwise were around tested by PCR; and (d) since infection due to a single exposure is common, were all individuals with even a single exposure to Dixson tracked and tested over the 14 day following exposure? Without these data, no person can claim that they were "100% safe during the entire pandemic," especially someone without the experience and qualifications to opine on such issues.

82. Some people believe that if they observed vaccinated co-workers testing positive for COVID-19 (e.g., during the Delta and Omicron waves in fall 2021 and early 2022), that means that either unvaccinated persons are at no greater risk for getting and transmitting COVID-19, or that vaccines do not work. As described above, the rate of infection (asymptomatic and symptomatic) is statistically and meaningfully lower in vaccinated individuals and populations compared to unvaccinated individuals and populations. The personal observation that vaccinated individuals got COVID-19 is irrelevant. I understand that almost every person that Dixson worked with at that time was vaccinated. As a result, any workplace infection that she was aware of was in a vaccinated colleague. This immediately biases her perception. Another way to frame this is to consider the following situation: imagine if there are 100 vaccinated people and 2 unvaccinated people in a workplace. If 5 people in the vaccinated group get infected and 1 in the unvaccinated group gets infected, does this mean that being vaccinated isn't protective? Not at all. The rate of infection in the vaccinated group is 5 per 100 and 50 per 100 in the unvaccinated group. What would happen if vaccinated people were better at getting tested compared to unvaccinated people who did not "believe" in COVID-19 as a risk? This would dramatically change the perception of risk. Did Plaintiff get tested whenever she had respiratory infection symptoms, included "cold symptoms"? Did she get tested following exposure in the household? All these reasons are why we use scientific studies that test and follow large groups of people to

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determine the impact of an intervention, and in fact commonly required multiple studies that come to the same conclusion. In the United States, these studies are evaluated by the U.S. Food and Drug Administration (FDA), the CDC's Advisory Council on Immunization Practice (ACIP) and other scientific expert before recommendations are made. Attached hereto as **Exhibit C** is a true and correct copy of the recommendations. A similar process occurs in other countries. Of note, all countries with similar processes have made similar recommendations for COVID-19 vaccination. Due to this process, by the end of 2022, COVID-19 vaccines prevented 18.5 million COVID-19 hospitalizations and 3.2 million deaths in the U.S. alone. Attached hereto as **Exhibit B** is a true and correct copy of the CDC's Oct. 20, 2023, Morbidity and Mortality Weekly Report. How would this have happened if we had no scientific studies and individuals relied only on their own experience? How would we know what antibiotic to use? Or chemotherapy for cancer?

83. Some people suggest that instead of relying on data shared by public health authorities, an employer should rely on what it observes in its workplace regarding COVID-19 positive cases and vaccination status to guide its assessment of COVID-19 risks and ways to reduce them. For the reasons stated above, using small unscientific samples or one's personal experience are not valid bases for decision making. In the case of pandemics, facilities and employers must use public health recommendations, based on the best available science, to make policy decisions. Employers do not generally have the expertise to collect and to analyze infectious disease data. Research studies on pandemics and vaccines required large teams with representation from a broad array of expertise, ranging from statistics, epidemiology, immunology, laboratory medicine, to clinical personnel. This data is collected and then submitted to a journal that then sends the paper to a group of individuals who are not involved in the study but have expertise in the area being studied. These experts review the data and make a recommendation to publish, improve, or reject the study for publication. When a group of studies support a similar conclusion, public health officials and other experts can make solid recommendations to protect our communities. To act against these recommendations is to take a

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stand against the basic principles of medical science and science in general that underpin all the scientific advances in our society.

- 84. Notwithstanding anecdotal observations from a workplace from late 2021 through April 2022, which may not be accurate based on asymptomatic COVID infections, an unvaccinated person was still more likely than a fully vaccinated person to contract and transmit COVID, and to experience serious illness or death from COVID.
- 85. I am aware that some people have expressed opposition to receiving the COVID-19 vaccines based on the use of HEK293 cells in the development or testing of the Pfizer and Moderna vaccines. HEK293 cells are immortalized human embryonic kidney cells that were isolated in the 1970s. Cell lines from HEK293 cells are widely used in research and biotechnology, including in medication testing. I have used such cells in my own research. HEK293 cells were used in the development of Pfizer and Moderna vaccines to confirm that certain genetic instructions would work in human cells—they were not used to actually produce either vaccine. ¹²⁴ I also understand that medications that have similarly used HEK293 cell lines in testing include acetaminophen (Tylenol), acetylsalicylic acid (aspirin), and ibuprofen (Advil), and that they are used for treatment research for diseases such as Alzheimer's and hypertension. ¹²⁵
- 86. The fact is that we do not know if this immortalized cell line used cells from a spontaneous abortion (a miscarriage) or an elective abortion. That difference may be important to the person who wants to get vaccinated otherwise.

¹²⁴ See Priyanka Runwal, Here are the facts about fetal cell lines and COVID-19 vaccines, National Geographic, Nov. 19, 2021, https://www.nationalgeographic.com/science/article/here-are-the-facts-about-fetal-cell-lines-and-covid-19-vaccines.

¹²⁵ *Id.* Other well-known drugs and medications using HEK293 cell lines in testing include: Naproxen (Aleve); Pseudoephedrine (Sudafed); Diphenhydramine (Benadryl); Loratradine (Claritin); Dextromethrophan (Robitussin); Guaifenesin (Mucinex); Calcium Carbonate (Tums); Bismuth Subsalicylate (Pepto-Bismol); Levothyroxine (Synthroid, Levoxyl); Atorvastatin (Lipitor); Amlodipine (Norvasc); Metoprolol (Toprol, Lopressor); Omeprazole (Prilosec, Zegerid); Losartan (Cozaar); Albuterol / Salbutamol (ProAir, Ventolin); Sacubitril (Valsartan, Entesto); Tenapanor (Ibsrela); Etanercept (Enbrel); Azithromycin (Zithromax); Hydroxychloroquine (Plaquenil); Remdesivir (Veklury); Ivermectin (Stromectol). *See* Matthew Schneider, *If Any Drug Tested on HEK-293 Is Immoral, Goodbye Modern Medicine*, Patheos Blog (Nov. 6, 2021), https://www.patheos.com/blogs/throughcatholiclenses/2021/01/if-any-drug-tested-on-hek-293-is-immoral-goodbye-modern-medicine/ (collecting medical studies).

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VII. THE CITY'S DECISION THAT IT COULD NOT ACCOMMODATE MS. DIXSON IN HER POLICE OFFICER JOB

- 87. I understand that the City determined that it was unable to grant an accommodation for Plaintiff Cheyanne Dixson, a City police officer, beyond February 2022 because it would cause an undue hardship on the conduct of the City's business and put the health and safety of other City employees and community members at risk.
- 88. I understand that the City's assessment of the burden on the City included the following considerations:

In making its determination, the City considered:

- Ms. Dixson's direct contact with the public on a daily basis.
- The contact Ms. Dixson had with other City employees.
- Developments in COVID-19 that increased the chances of contracting and spreading the virus.
- The cost of continued testing, both from a work efficiency and financial perspective.
- The City's plan to reopen offices to both staff and the public beginning November 1, 2021.
- 89. I understand that this case involves an employee who, as a police officer, would have the job duty of patrolling assigned geographical areas in the City by car, bike, or on foot or other means to aide in preventing crime and to enforce criminal traffic laws and regulations. I also understand that police officers participate in direct contact with the public and members of the community on a day-to-day basis when doing things such as:
 - Responding to the scene of a crime or accident
 - Administering first aid
 - Interviewing victims and eyewitnesses
 - Physically detaining law violators
 - Receiving, searching, booking and/or supervising prisoners

DECLARATION OF JOHN LYNCH, MD IN SUPPORT OF DEFENDANT CITY OF ISSAQUAH'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE DR. HARVEY RISCH - 39 CASE NO. 2:24-cv-01673-TL

SUMMIT LAW GROUP, PLLC

315 FIFTH AVENUE SOUTH, SUITE 1000 SEATTLE, WASHINGTON 98104-2682 Telephone: (206) 676-7000 Fax: (206) 676-7001

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- 91. As explained above, at the time the vaccination policy was announced, COVID-19 cases were spiking due to the Delta variant despite other strategies in place. This was followed by the Omicron waves, which continued in this area into 2022. The public health information available from August 2021 through February 2022, as well as the information available today, established that an unvaccinated person posed materially higher risks of transmitting COVID-19, including increasing the potential for causing an outbreak, contracting COVID-19, and developing severe disease, compared with a vaccinated person. This is true regardless of whether the unvaccinated person worked indoors or outdoors. An unvaccinated person would increase the likelihood of COVID-19 transmission and infection amongst others by simply being present, even if masked, in a lunchroom, office space, bathroom, or corridor. Further, police officers have some of the highest recorded times spent outdoors but also have some of the highest risks of COVID exposure and infection. 126,127,128
- 92. If an unvaccinated employee enters a work site, office, or public area, there is a greater risk of COVID transmission, leading to infection of co-workers, employees, or members of

¹²⁶ See Boydstun, J. L. & Wells, M. J, A Review of COVID-19 Deaths among Law Enforcement Officers in the United States, Polic. J. 97, 259–278 (2024).

¹²⁷ See https://abcnews.go.com/Health/covid-leading-cause-law-enforcement-deaths-2022-3rd/story?id=96363324.

¹²⁸ See Violanti JM, Fekedulegn D, McCanlies E, Andrew ME, *Proportionate mortality and national rate of death from COVID-19 among US law enforcement officers: 2020 Policing.* 2022 May 24;45(5):881-891. doi: 10.1108/pijpsm-02-2022-0022. PMID: 37192870; PMCID: PMC10174272.

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- 93. While transmitting COVID-19 to a co-worker implicates serious issues, including the outcomes of infection in that person, and the transmission from that person to other people in their lives (including potentially higher risk family members), transmitting COVID-19 to an unsuspecting child, member of the community, or a person who has been arrested, and who therefore does not have the ability to take additional precautions to protect themselves, implicates potentially even greater issues (as described earlier in this document).
- 94. Based on recommendations from the CDC, the Washington Department of Health, Public Health Seattle & King County, and my own research and understanding, it is my opinion that vaccination was and is the single best tool available for stemming the spread of COVID-19 and its variants, especially when used in combination with other mitigations. Vaccination against COVID-19 is fast (each dose takes about 20 seconds to administer), extremely safe, and highly effective at preventing transmission of the virus and especially severe disease and death. It remains the most important and effective public health tool at our disposal in the COVID-19 pandemic. No other public health strategy could effectively meet the City's goals of safely providing City services while also protecting the health, safety, and well-being of employees and the public at large.
- 95. The public health information available at the time, as well as the information available today, established that masking, testing, or social distancing alone or the combination of masking, testing, and social distancing were not equivalent to the combination of vaccination, masking, testing, and social distancing in terms of protecting employees and other persons with whom an employee comes into contact while performing job duties. In my expert opinion, regular COVID-19 precautions such as masking and other mitigation strategy but cannot replace

vaccination. There are no scientific data that I am aware of that describe an equivalency between being vaccinated in addition to other mitigations and not being vaccinated with those same mitigations. As described above, masking is not a substitute for vaccination, and there are no studies demonstrating that non-pharmaceutical interventions (such as masking, sick leave, and access to testing) are, in themselves, sufficient to reduce the risk of infection and transmission in the workplace compared to vaccination with any combination of those mitigations. Social distancing can serve as a layer of mitigation, but this is complicated by the fact that we do not know what a "safe" distance is and by the fact that aerosolized virus remains floating in the air, creating a risk for people who enter a room after the infected person leaves, and for people in adjacent spaces with shared air. Vaccination addresses all these concerns.

- 96. Testing is far from equivalent to being vaccinated and has not been demonstrated to be an effective tool to prevent COVID-19 transmission in the workplace compared to the effects of vaccination. As described earlier in this document, regular testing has several significant weaknesses. Even putting aside the limitations of PCR and antigen tests, a weekly testing regimen is not frequent enough to prevent an employee from reporting to work while infected with COVID-19. For example, if testing is performed every Wednesday, the person could be infectious and working on Monday, Tuesday, Thursday, Friday, Saturday, and Sunday.
- 97. Moreover, even a more frequent testing regimen would also not eliminate these risks. Because PCR tests can take multiple days to return results, even if the Plaintiff submitted to PCR tests every day, that would not avoid the risk that they would be infected with and/or transmit COVID-19 while at work. And because of the risks of false negative PCR tests and asymptomatic infection and transmission, a regimen of daily PCR testing would similarly not have avoided these risks. Furthermore, it is not clear that the quantity of antigen tests required to permit daily or weekly testing would have been available at the time of Plaintiff's accommodation requests. For these reasons, even with the required administration and data tracking processes in place, regular PCR testing or antigen testing could easily fail to detect an infected person.

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98. It is my opinion that the City's undue hardship conclusion was supported by the scientific evidence and public health data available from August 2021 to February 2022 and today. Given above-mentioned evidence and Plaintiff's job duties, which entailed interactions with coworkers and members of the public, any of whom may have risk factors for severe COVID-19 outcomes, including death, it is my opinion that, had the City allowed Plaintiff to continue her employment unvaccinated, it would have significantly increased the risk that Plaintiff would infect co-workers and members of the public with COVID-19 or contract the virus herself. Data available at the time established that an unvaccinated person posed materially higher risks of transmitting COVID-19, including increasing the potential for causing an outbreak, contracting COVID-19, developing severe disease, and facing hospitalization or death, compared with a vaccinated person. Mitigation techniques such as masking, testing, and social distancing are inferior to vaccination, and even with such safety measures in place, allowing Plaintiff to work unvaccinated would have still posed significant increased safety risks. The combination of masking, testing, and at times working outdoors was not equivalent to the combination of vaccination, masking, and at times working outdoors in terms of protecting employees and other persons with whom a police officer comes into contact while performing job duties.

VIII. REBUTTAL TO DR. HARVEY RISCH'S EXPERT REPORTS

- 99. I have reviewed the report and addendum prepared by Dr. Harvey Risch in this matter: "Re: Cheyanne [Dixson] Rosa v. Cit of Issaquah Police Department et al. ("Issaquah") Case, Case No. 2:2022cv-1771, in response to expert report provided by Dr. John Lynch, January 21, 2025" (Feb. 19, 2025) (the report) and "Re: Cheyanne [Dixson] Rosa v. Cit of Issaquah Police Department et al. ("Issaquah") Case, Case No. 2:2022cv-1771, Addendum and Clarification" (March 21, 2025) (the addendum). I also reviewed Dr. Risch's CV and his deposition transcript in this matter.
- 100. I provided two expert reports in this matter. My original expert report was issued on January 21, 2025. My rebuttal expert report, which contains my opinions rebutting Dr. Risch's

DECLARATION OF JOHN LYNCH, MD IN SUPPORT OF DEFENDANT CITY OF ISSAQUAH'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE DR. HARVEY RISCH - 43 CASE NO. 2:24-cv-01673-TL

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25 26 Attached hereto as **Exhibit G** is a true and correct copy of my rebuttal report, which I incorporate herein subject to the declaration below regarding its truthfulness. Dr. Risch's Report highlights his 400+ peer-reviewed publications, but those

testimony and specifically responding to assertions in his report, was issued on March 26, 2025.

- predominantly focus on cancer. Of the 6 peer-reviewed articles that relate to COVID-19, one relates to the alleged politics behind vaccine mandates and the rest relate to treatments for COVID-19 and espouse theories that have been debunked or called into concern, as explained in my rebuttal report.
- Dr. Risch is the Chief Epidemiology Officer of the Wellness Company, which sells 102. non-FDA-approved supplements, including ones purporting to treat alleged harms caused by the COVID-19 vaccines (by supposedly removing the spike protein from people who have been vaccinated), whose efficacy are unsupported by any scientific data.
- Dr. Risch, despite having a long history of research in cancer risk epidemiology, repeatedly uses information from sources that are strongly associated with anti-vaccine propaganda, as explained in greater detail in my rebuttal report.
- 104. Dr. Risch's Report regularly uses information that was not available at the time of the City's implementation of the vaccine mandate. Data reviewed in hindsight does not give an appropriate view or analysis of the data available during the relevant period (here August 2021-February 2022).
- 105. Dr. Risch's statement that it was improper for the City to allegedly considered "relative risks" posed by unvaccinated individuals lacks any support in the relevant scientific community. This perspective implies a lack of understanding of how vaccines work and how vaccine effectiveness is determined. For example, in the original research studies used to demonstrate the impact of the mRNA vaccines the researchers compared COVID-19 infections, severe disease, and death in the vaccinated group and the unvaccinated population. At no point did every unvaccinated person get COVID-19. But when compared to the number of people infected

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in the unvaccinated group, ~95% fewer people in the vaccinated group got infected. The difference in number infected in the unvaccinated group versus in the vaccinated group is the relative risk reduction. The reason it is relative and not an absolute reduction is that the absolute risk of infection varies over time depending on how much COVID-19 is circulating, what variants are present, and whether there are broadly used NPIs like required masking in indoor public spaces. Some people who have stated positions against COVID-19 or other vaccines point to the absolute risk reduction, which can be interpreted as small and thus ineffective. This perspective again missed the fact that even in a pandemic, in any given short time period (weeks to months) not every non-immune person is exposed and not every non-immune person is infected. To respond to Dr. Risch's comment, the relative risk reduction demonstrated in COVID-19 vaccine studies is the standard assessment of vaccine efficacy and effectiveness. Dr. Risch again makes the same error in thinking in his deposition (page 54, lines 19 through 24). Using his numbers, public health data showed that vaccinated individuals had a 64% reduced risk of infection compared to unvaccinated individuals. It does not mean that 36% of vaccinated people were going to get infected. Again, this implies that 100% of people were exposed to a potential transmission event, which was never the case at any time in the pandemic. On the following page, on lines 3, 4, and 5, he states that "a third of more [vaccinations] may be useless." This is an incorrect understanding of basic vaccine effectiveness.

106. Dr. Risch's "risk burden analysis" is not generally accepted in the public health or occupational health community in the context of assessing workplace risks during a pandemic. I am not aware of any others who have applied this methodology in the COVID-19 risk assessment context, let alone the accommodation context. I am similarly unaware of this analysis being recommended by the CDC or any other public health agency/association or being the subject of any peer-reviewed publications related to the COVID-19 pandemic. Dr. Risch's approach also does not consider other City of Issaquah employees who may or may not have decided to get

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Dr. Risch's 3.65% breakthrough infection "rate" is incorrect and inapplicable for several reasons, in addition to those noted in my rebuttal report. Contrary to Dr. Risch's assertion regarding the number of people in the U.S. that were fully vaccinated by the end of 2021, by the end of 2021, ~62% of the U.S. population, or 205,811,394 people, were fully vaccinated. See **Exhibit H**, which is a true and correct copy of CDC vaccination data published on https://usafacts.org/visualizations/covid-vaccine-tracker-states/. Using the table on page 9, Dr. Risch states that 5,105,414 fully vaccinated people had a breakthrough infection by the end of 2021. As such, the cumulative breakthrough infection "rate" at the end of 2021 was only 2.48% (5,105,414/205,811,394).¹²⁹ That means that roughly 200,871,921 fully vaccinated people did not have a breakthrough infection. I consider an intervention that prevents 97.6% of harm events to be highly effective. Further, Dr. Risch's breakthrough infection "rate" is not actually a rate. Rather, it is a nationwide cumulative estimate of breakthrough infections. It is not a relevant data point for many reasons, including because a cumulative breakthrough infection estimate is not sensitive to many factors that actual breakthrough rates depend on like case rates, variants, nonpharmaceutical interventions, and vaccination rates. 130 Finally, Dr. Risch's breakthrough infection "rate" is also inapplicable because it is retrospective estimate of the whole U.S. population that was not available to policymakers or experts at the time.

108. In the first paragraph on page 6 of Dr. Risch's report, he provides relative risk (RR) estimates using the following equation: RR=1/(1-vaccine efficacy). Using this formula, which is technically the reciprocal of the relative risk, he stated that there was a RR of 4.6 for getting COVID-19 in unvaccinated people compared to vaccinated people in 2021. When the delta variant

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¹²⁹ Similarly, as Dr. Risch notes in his Report, in Washington State, between January 2021 and January 2022, only about 2.5% of the vaccinated population had a breakthrough infection.

¹³⁰ See Jones, J. M. et al. Updated US Infection- and Vaccine-Induced SARS-CoV-2 Seroprevalence Estimates Based on Blood Donations, July 2020-December 2021. JAMA **328**, 298–301 (2022).

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was predominant, the RR decreased to approximately 2.8-fold increased risk in unvaccinated people. In both situations, being unvaccinated was associated with a higher risk of COVID-19 infection. It is important to recognize that these are both *fold* increases, so they are *multipliers* of infection risk compared to vaccinated people. An alternative, and perhaps more intuitive way to think about vaccine effectiveness, is to understand that a vaccine with 78% effectiveness prevents 78% of the infections that would have otherwise occurred in the absence of the vaccine. During the delta phase, vaccine effectiveness was estimated to be between ~65% and ~80% (and potentially higher) depending on the data source and population being evaluated. ^{131,132,133,134} That range means that vaccination continued to prevent between 65% and 80% of infections that would have otherwise occurred. Using the upper estimate gives a RR of infection for unvaccinated people as 5 times the risk compared to vaccinated people. Using either approach, the reduction in infections due to vaccination was superior to being unvaccinated. Furthermore, there are no data to support an approach, outside of vaccination, that would provide a similar level of protection for an Ms. Dixson in her work environment.

109. In addition to being based on flawed and/or inapplicable data, Dr. Risch's risk analysis also fails to consider material information and assumes, without support, that people will not work while infected or with an asymptomatic infection and that an infected person's risk to others is spread uniformly across an organization and across all situations/encounters. My understanding is that Ms. Dixson worked in multiple locations with coworkers, incarcerated individuals, and members of the public (including elderly individuals, unhoused individuals, and

¹³¹ See Zheng, C. et al. Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis. Int. J. Infect. Dis. 114, 252–260 (2022).

¹³² See Kow, C. S., Ramachandram, D. S. & Hasan, S. S. The effectiveness of mRNA-1273 vaccine against COVID-19 caused by Delta variant: A systematic review and meta-analysis. J. Méd. Virol. **94**, 2269–2274 (2022).

¹³³ See Rosenberg, E. S. et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. Morb. Mortal. Wkly. Rep. **70**, 1306–1311 (2021).

¹³⁴ See Plumb, I. D. et al. Estimated COVID-19 vaccine effectiveness against seroconversion from SARS-CoV-2 Infection, March–October, 2021. *Vaccine* **41**, 2596–2604 (2023).

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- 110. Dr. Risch's analysis also solely accounts for infection rates, but not transmission. Unvaccinated people have higher infectious viral loads that take longer to clear than vaccinated people. As such, this means that an infected, unvaccinated person carries a higher risk of transmission, in addition to their higher risk of infection.
- 111. Dr. Rish stated in his testimony (page 79, line 22 through page 80, line 1) that "we certainly had a whole spectrum of outpatient treatment that was being used at various times that prevented people from being hospitalized and from dying, and that was an aggressive approach that should have been used even more." At no time during the pandemic did we have "a whole spectrum" of treatments to prevent COVID-19 hospitalizations or dying. We cycled through a handful of outpatient and inpatient treatments, none of which, aside from steroids for critically ill patients, was highly effective and continue to be "suggested" rather that strongly recommended. Dr. Risch's comment also implies that providers in the United Staes were not adequately treating people with COVID-19 and if we did, the pandemic would not have been nearly as destructive as it was. There is no data to support Dr. Risch's statements.
- 112. Finally, Dr. Risch's assertion that if Ms. Dixson were allowed to work, her fraction of the City's police officers' "absolute" infection risk would be less than the number of vaccinated police officers with breakthrough infections is specious. This figure improperly considers only the number of police officers, rather than all Issaquah Police Department staff with whom Dixson

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¹³⁵ See Puhach, O., Meyer, B. & Eckerle, I. SARS-CoV-2 viral load and shedding kinetics. Nat. Rev. Microbiol. **21**, 147–161 (2023).

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interacted. Dr. Risch's absolute infection risk rate calculation is also directly related to the number of people who are vaccinated and would have been far higher if less than 97% of police officers were vaccinated due to the mandate. Further, Dr. Risch's absolute infection risk rate analysis fails to compare Ms. Dixson's purported infection risk to the purported infection risk of each individual police officer. When such a comparison is done using the figures in Dr. Risch's Report, it appears that Ms. Dixson had a 5x higher absolute infection risk (11%) than each vaccinated officer (2.4%). He attempts to explain this difference in risk by spreading the risk across all interactions by members of the Issaquah Police Department. The fact is that the risk would be carried by those Ms. Dixson interacts with regularly and by members of the community who she may interact with only once, including individuals who may not be able to protect themselves (e.g., unable to wear a mask), all while she is at higher risk of infection and transmitting to others. Dr. Risch appears to apply a subjective lens to this assessment of risk and potential harm to Plaintiff's co-workers and members of the public. He attempts to make a mathematical argument, as an academic epidemiologist, in place of assessing what accommodations were possible that reduced that level of risk to approximate the risk of vaccinated individuals doing the same work. In fact, his recommendation is that Dixson could continue performing her same job duties without accommodations like masking, testing, or social distancing, despite the increased risk. I would argue that this position reflects Dr. Risch's lack of occupational health and pandemic response experience.

113. Despite being part of a team that developed a COVID-19 vaccination requirement for a large health system, guiding UW Medicine's response to the COVID-19 pandemic, and working with numerous colleagues across the country and multiple organizations that also implemented vaccination requirements, I have never seen or heard of the approach outlined by Dr. Risch used. It is also wildly unrealistic to expect every employer in the United States to have hired a "credentialed epidemiologist" (page 166, line 16) to perform these calculations.

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1	114. For these reasons, and the reasons outlined in my rebuttal report, Dr. Risch's risk
2	analysis is flawed and is irrelevant to the issues in this case. My rebuttal report provides
3	additional information as to the flawed nature of Dr. Risch's other assertions/opinions.
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5	I declare under penalty of perjury under the laws of the state of Washington that the
6	foregoing is true and correct to the best of my knowledge.
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8	Executed this 22nd day of May, 2025, at Seattle, Washington.
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EXHIBIT A

CURRICULUM VITEA JOHN LYNCH, MD, MPH, FIDSA November 2024

1. Personal Data

Place of birth: Providence, Rhode Island

2. Education:

1987-1991	BA, Anthropology/History, University of Rhode Island, Kingston, RI
1998-2001	MD, University of Washington, Seattle, WA
2008-2011	MPH, Epidemiology/Global Health, University of Washington, Seattle,
WA	

3. Postgraduate training

2002-2005	Internship in Internal Medicine, Massachusetts General Hospital, Boston,
	MA.
2005-2009	Fellow in Infectious Diseases, University of Washington, Seattle, WA.
2006-2009	Post-doctoral Fellow, Overbaugh Lab, Fred Hutchinson Cancer Research
	Center, Seattle, WA.

4. Faculty Positions Held

2009-2010	Acting Instructor, Department of Medicine, Division of Allergy and
	Infectious Diseases, University of Washington, Seattle, WA
2009-2011	Research Associate, Human Biology Division, Fred Hutchinson Cancer
	Research Center, Seattle, WA
2010-2014	Assistant Professor, Department of Medicine, University of Washington,
	Seattle, WA
2014-2021	Associate Professor, Department of Medicine, University of Washington,
	Seattle, WA
2021-	Professor, Department of Medicine, University of Washington, Seattle,
	WA

5. Hospital Positions

2009-	Attending Physician, Harborview Medical Center
2009-	Attending Physician, University of Washington Medical Center
2010-	Medical Director, Employee Health Services, Harborview Medical Center
2010-2018	Medical Director, Antimicrobial Stewardship Program, Harborview
	Medical Center

2010-2014	Assistant Medical Director, Infection Control, Harborview Medical Center
2010-2014	Medical Director, Infectious Disease Clinic, Harborview Medical Center
2014-	Medical Director, Infection Prevention & Control, Harborview
	Medical Center
2014-	Co-Chair, UW Medicine Infection Prevention & Control Committee
2014-	Chair, Infection Prevention & Control Committee, Harborview
	Medical Center
2016-2020	Co-Chair, UW Medicine Antimicrobial Stewardship Committee
2017-2020	President of the Harborview Medical Center Medical Staff 2019-2020
2019-2020	Medical Staff President, Harborview Medical Center
2019-	Medical Director, Sepsis Program, Harborview Medical Center
2019-	Associate Medical Director, Harborview Medical Center
2020-2023	Clinical Lead, Medical-Technical Team, UW Medicine COVID-19
	Emergency Operations Center

6. Honors

1990	Phi Alpha Theta History Honor Society, University of Rhode Island
1991	President's Award for Academic Excellence in Anthropology, University of
	Rhode Island
1999	Medical Student Association President (Member 1998-2002), University
	of Washington School of Medicine
1999, 2002	International AIDS Research and Training Program Fellowships
2002	Gary E. Leinbach Award, University of Washington School of Medicine
2002	Alpha Omega Alpha Medical Honor Society, University of Washington
	School of Medicine
2002	ACP-ASIM Washington Chapter Outstanding Student in Internal Medicine
2002	M.D. Degree with Honors, University of Washington School of Medicine
2005	Morton N. Swartz Humanism in Medicine Award, Massachusetts General
	Hospital
2006-2008	National Institutes of Health Loan Repayment Grantee
2008-2010	University of Washington Institute for Translational Health Sciences
	Fellow
2014	Harborview Medical Center CARES Award, Employee Health
	Service
2015	Harborview Medical Center CARES Award, Infection Control
	Program
2018	Washington State Hospital Association Community Health
	Leadership Silver Award for UW Tele-Antimicrobial Stewardship Program

	(UW TASP)
2019	Elected to the UW Chapter of the Gold Humanism Honor Society
2020	University of Washington Distinguished Staff Award (R&T Radiological
	Response Team, Clinical Lead)
2020	William O. Robertson Patient Safety Award, Washington State Medical
	Association
2021	University of Washington David B. Thorud Leadership Award
2021	Grassroots Champion Award for Washington State, American Hospital
	Association

7. Board Certification

2005-2105	Diplomate, American Board of Internal Medicine
2007-2028	Diplomate, American Board of Internal Medicine, Infectious Disease

8. Current Licensure

2002-2005	Massachusetts State License, Physician & Surgeon
2005-	Washington State License, Physician & Surgeon

9. Diversity, Equity, and Inclusion Activities

2017-	Co-Director, Center for Stewardship in Medicine
2019-2022	Diversity Committee, Division of Allergy & Infectious Diseases, UW School
	of Medicine
2020	Meetings with President of the Quinault Nation and with Washington
	State Tribal Leaders and medical directors regarding COVID-19

Since 2017 I have co-led the UW Tele-Antimicrobial Stewardship Program (TASP) which has since broadened to become the Center for Stewardship in Medicine. This program provides infectious diseases, antimicrobial stewardship, and infection prevention telementoring and other resources to small, rural, and critical access hospitals in the United States. We also provided guidance throughout the pandemic. As part of the UW Medicine COVID Emergency Operations Center, I was also very active in outreach to and education of communities that were disproportionally impacted by the pandemic.

10. Professional Organizations

2005- Infectious Diseases Society of America

- Chair, COVID PPE Guidelines Committee, 2020-
- Board of Directors, 2019-2022
- Clinical Affairs Committee Member, 2012-2015

- Program Committee Member, ID Week 2015-2019
- ID Week abstract reviewer, 2013-2019
- Antimicrobial Resistance Committee Working Group, 2015

2005- Infectious Diseases Society of Washington

2018- Society for Healthcare Epidemiology of America

2020-2021 International Task Force on COVID-19 Management, American Thoracic

Society

2020-2022 Washington State Medical Association

11. Education and Training Activities

a. Didactic Teaching

2018-	Lecturer, MEDSCI 520, WWAMI Invaders and Defenders,
	University of Washington School of Medicine
2015	Course Chair, HUBIO 534, Microbiology, University of Washington
	School of Medicine
2015-2017	Block Director, MEDSCI 520, WWAMI Invaders and Defenders, University
	of Washington School of Medicine
2010-2013	Course Chair, MED 540/EPI 505, Prevention of Healthcare Associated
	Infections, University of Washington Schools of Medicine and Public
	Health, Winter Quarters, Seattle, WA
2010-2015	Lecturer, CONJOINT 550, Clinical Infectious Diseases, University of
	Washington School of Medicine, Seattle, WA
2019, 2020	Lecturer, CONJOINT 550, Clinical Infectious Diseases, University of
	Washington School of Medicine, Seattle, WA
2010-2017	Lecturer, Quarterly Core Medicine Clerkship Teaching for 3 rd year medical
	students, University of Washington School of Medicine, Seattle, WA
2013-2014	Course Co-Chair, EPI 529/HSERV 536, Emerging Infections of International
	Public Health Importance, University of Washington School of Public
	Health, Winter Quarters, Seattle, WA
2013	Co-Director, Global Health and Disparities Ambulatory Block,
	Internal Medicine Residency Program, University of Washington School of
	Medicine, Seattle, WA
2009-2016	Clinical teaching, Internal Medicine, Harborview Medical Center
2009-	Clinical teaching, Infectious Diseases consult, Harborview Medical
	Center
2008	Initiated Infectious Diseases Fellow's Board Review Series,
	University of Washington

b. Thesis Committee Membership

n/a

c. Advising/Mentorship

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2015-2017	Yuan Zhou, MD, ID Fellow (Current: private practice)
2016-2017	Margaret Lind, MPH, PhD (Current: post-doctoral fellow, Yale University)
2017-2018	Ted Wright, MD, ID Fellow (Current: private practice)
2017-2018	Chloe Bryson-Cahn, MD, ID Fellow (Current: Assistant Professor, UW)
2019-2020	Nandita Mani, MD, ID Fellow (Current: Clinical Assistant Professor, UW)
2019-2023	Dustin Long, MD, Assistant Professor, Anesthesiology and Pain
	Medicine/Critical Care, UW, Recipient 2019 Society for Healthcare
	Epidemiology of America Epi Competition Award (\$20,000)
2021-2022	Alyssa Castillo, MD, ID Fellow (Current: Assistant Professor, University of
	Colorado)
2021-2022	Peter Bulger, MD, ID Fellow (Current: private practice)
2022-2023	William Simmons, MD, ID Fellow (Current: Assistant Professor, University
	of California, San Francisco)
2023-2024	Hayato Mitako, MD (Current: Assistant Professor, University of Colorado)

d. Curriculum and Training Program Development

n/a

e. Other

n/a

12. Editorial Responsibilities

n/a

13. Special Responsibilities and Service

a. International

n/a

b. National

2010-2014 Malaria section, CDC/NIH/HIVMA/IDSA Guidelines for

	Prevention and Treatment of Opportunistic Infections in			
	HIV-positive Adults and Adolescents, published spring 2013.			
2012-2015	Clinical Affairs Committee, Infectious Disease Society of America			
2015-2019	Program Committee, Infectious Disease Society of America			
2020-2024	Chair, COVID-19 PPE Guideline Subcommittee, Infectious Diseases Society of America			
2020-2021	NFL COVID-19 Advisory Committee			
c. Regional				
2013-2014	Lecturer and Consultant, Washington State Hospital Association, Leading Edge Advanced Practice Topics (LEAPT)/Partnership for Patients, focused on central-line associated bloodstream infections, <i>Clostridium difficile</i> infections and antimicrobial stewardship			
2014-2015	Lecturer and Consultant, Washington State Hospital Association, Leading Edge Advanced Practice Topics (LEAPT)/Partnership for Patients, focused on antimicrobial stewardship and <i>Clostridium</i> <i>difficile</i> infection reduction			
2014-2020	Hospital Infection Leaders Committee, Washington State Hospital Association, Seattle, WA			
2012-2016	King County Medical Society Public Health Liaison Committee, Infectious Disease Society of Washington Representative			

d. University of Washington

2014-Present	Healthcare Associated Infection Advisory Board, Washington State Department of Health, Tukwila, WA
2014-Present	Antimicrobial Stewardship Advisory Committee, Washington State Department of Health, Seattle, WA
2020-Present	UW Advisory Committee on Communicable Diseases
2019-Present	Associate Medical Director, Harborview Medical Center, Seattle,
	WA
2019-Present	Chair, Sepsis Committee, Harborview Medical Center, Seattle, WA
2019-Present	Rotating Chair, UW Medicine Sepsis Committee, UW Medicine,
	Seattle, WA
2016-Present	Co-Director, UW Center for Stewardship in Medicine
2015-Present	Harborview Medical Center Quality Improvement/Patient Safety

	Leadership Committee
2012-Present	UW Medicine Advisory Committee on Blood-borne Pathogens
2011-Present	UW Medicine Infection Control Committee, University of
	Washington, Seattle, WA (Co-Chair, 2014-Present)
2010-Present	Infection Control Committee, Harborview Medical Center, Seattle,
	WA (Chair, 2014-Present)
2010-Present	Tuberculosis Subcommittee, Harborview Medical Center, Seattle,
	WA (Co-Chair, 2014-Present)
2010-2018	Pharmacy and Therapeutics Committee, Infectious Diseases
	Subcommittee, University of Washington, Seattle, WA
2010-Present	Organizational Improvement Committee, Harborview
	Medical Center, Seattle, WA
2010-Present	Organizational Improvement Metrics Committee, Harborview
	Medical Center, Seattle, WA
2010-Present	Campus Health Services Executive Committee, University of
	Washington, Seattle, WA
2010-Present	Central Venous Access Device Committee, Harborview Medical
	Center, Seattle, WA
2010-Present	Environment of Care Committee, Harborview Medical Center,
	Seattle, WA
	Seattle, WA
<u>Past</u>	Seattle, WA
Past 2007-2018	Seattle, WA Infectious Diseases Fellowship Curriculum Committee, University
<u> </u>	
<u> </u>	Infectious Diseases Fellowship Curriculum Committee, University
2007-2018	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA
2007-2018	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical
2007-2018 2010- 2018	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director)
2007-2018 2010- 2018	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director) Surgical Care Improvement Project (SCIP), Harborview Medical
2007-2018 2010- 2018 2010-2015	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director) Surgical Care Improvement Project (SCIP), Harborview Medical Center, Seattle, WA
2010-2018 2010-2015 2010-2023	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director) Surgical Care Improvement Project (SCIP), Harborview Medical Center, Seattle, WA WASH Committee, Harborview Medical Center, Seattle, WA
2010-2018 2010-2015 2010-2023	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director) Surgical Care Improvement Project (SCIP), Harborview Medical Center, Seattle, WA WASH Committee, Harborview Medical Center, Seattle, WA Core Measures Performance, Harborview Medical Center, Seattle,
2010-2018 2010-2018 2010-2015 2010-2023 2011-2014	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director) Surgical Care Improvement Project (SCIP), Harborview Medical Center, Seattle, WA WASH Committee, Harborview Medical Center, Seattle, WA Core Measures Performance, Harborview Medical Center, Seattle, WA
2010-2018 2010-2018 2010-2015 2010-2023 2011-2014	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director) Surgical Care Improvement Project (SCIP), Harborview Medical Center, Seattle, WA WASH Committee, Harborview Medical Center, Seattle, WA Core Measures Performance, Harborview Medical Center, Seattle, WA UW Medicine Hazardous Drug Control Program, Employee Health
2010-2018 2010-2018 2010-2015 2010-2023 2011-2014 2013-2015	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director) Surgical Care Improvement Project (SCIP), Harborview Medical Center, Seattle, WA WASH Committee, Harborview Medical Center, Seattle, WA Core Measures Performance, Harborview Medical Center, Seattle, WA UW Medicine Hazardous Drug Control Program, Employee Health Subgroup Lead
2010-2018 2010-2018 2010-2015 2010-2023 2011-2014 2013-2015	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director) Surgical Care Improvement Project (SCIP), Harborview Medical Center, Seattle, WA WASH Committee, Harborview Medical Center, Seattle, WA Core Measures Performance, Harborview Medical Center, Seattle, WA UW Medicine Hazardous Drug Control Program, Employee Health Subgroup Lead Center of Occupational Health and Education Advisory
2010-2018 2010-2018 2010-2015 2010-2023 2011-2014 2013-2015 2013-2015	Infectious Diseases Fellowship Curriculum Committee, University of Washington, Seattle, WA Seattle Antimicrobial Stewardship Program, Harborview Medical Center, Seattle, WA (Medical Director) Surgical Care Improvement Project (SCIP), Harborview Medical Center, Seattle, WA WASH Committee, Harborview Medical Center, Seattle, WA Core Measures Performance, Harborview Medical Center, Seattle, WA UW Medicine Hazardous Drug Control Program, Employee Health Subgroup Lead Center of Occupational Health and Education Advisory Committee, University of Washington

	Clinical Competency Committee
2014-2018	Co-Chair, Infectious Diseases Fellow's course, University of
	Washington, Seattle, WA
2010-2014	Ambulatory Care Advisory Council, Harborview Medical Center,
	Seattle, WA
2016-2017	UW SOM Committee 4 (LCME Accreditation)
2017-2019	Faculty Council on Academic Affairs, University of Washington
	School of Medicine, Seattle, WA
2016-2016	Co-Chair, UW Medicine Antimicrobial Stewardship Committee
2020-2023	Clinical Lead, UW Medicine COVID-19 Response

14. Clinical Activities

I continue to be a part of the HMC Infectious Diseases Consult Service as an attending, usually for 4 weeks per year. In 2020 I was unable to attend due to the volume of work with the COVID Emergency Operations Center and responding to the pandemic.

15. Research Funding

A. Current

1.UW Center for Stewardship in Medicine (CSiM)

Award-winning program that supports the implementation and maintenance of active antimicrobial stewardship programs in small, community and critical access hospitals in Washington and moving into Oregon and north Idaho. The program is composed of weekly didactic and case discussion sessions, a website with recorded didactics, policies, protocols and toolkits for stewardship activities, site visits to each facility, and intensive quality improvement cohorts. Since launching in February 2017, UW CSiM has continued to grow and expand across the United States.

Role: Primary Investigator

B. Past

2009-2010	National Institutes of Health, National Institute for Allergy and Infectious
	Diseases Clinical Investigator Award, 1 K08 AI081546-01A1 (\$649,350)
	Primary Investigator: John Lynch. "The Role of ADCC in Mother to Infant
	HIV Transmission", 5-year award, discontinued when current faculty
	position started.
2015-2023	ITECH Kenya Infection Prevention & Control/Antimicrobial Stewardship

Implementation in 2 Model Hospitals (Grant title: Securing Global Public Health Through Strengthening Information Systems and Reporting in Kenya)

Multi-year CDC funded project through the UW International Training and Education Center for Health to establish and mentor infection prevention & control IPC programs in 2 hospitals in Kenya (Thika and Kitale). Working with the Ministry of Health, ITECH Kenya, and the CDC teams, ITECH, an educational curriculum was developed and deployed for staff at both facilities. Current activity is focused on rolling-out 4 quality improvement projects (hand hygiene, waste management, surgical site infection surveillance and safe injection practices). Given the lack of IPC expertise and activities in many facilities in low resource settings, this program has the potential to develop a package of materials for wider implementation in similar environments.

Role: Subject matter expert and team lead

PI: Peter Rabinowitz

Funding: CDC 5NU2GGH001721-03-00 (2017-2020)

16. Bibliography

a. Peer-Reviewed Manuscripts

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- 20. Choudhuri JA, Chan JD, Schreuder AB, Hafermann MJ, Fulton C, Melius E, McNamara E, Pergamit RF, Lynch JB, Dellit TH. Shared hoppers: a novel risk factor for the transmission of Clostridium difficile. Infect Control Hosp Epidemiol.2014 Oct;35(10):1314-6. doi: 10.1086/678077. PubMed PMID: 25203194. [original work]

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- 53. Long D, Chan JD, Bryson-Cahn C, Lynch JB. Epidemiology of Surgical Site Infection in Spinal Fusion Surgery and Patterns of Discordance with Surgical Antibiotic Prophylaxis: A Retrospective Case-Level Analysis. Spine (Phila Pa 1976). 2020 Aug 12. doi: 10.1097/BRS.0000000000003603 (2020). [original work]
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- **75.** Long DR, Bryson-Cahn C, Waalkes A, Holmes EA, Penewit K, Tavolaro C, Bellabarba C, Zhang F, Chan JD, Fang FC, **Lynch JB**, Salipante SJ. Contribution of the patient microbiome to surgical site infection and antibiotic prophylaxis failure in spine surgery. Sci Transl Med. 2024 Apr 10;16(742):eadk8222. doi: 10.1126/scitranslmed.adk8222. Epub 2024 Apr 10. PMID: 38598612. [original work]
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- **77. Lynch JB.** Vaccine Mandates for Health Care Workers-An Effective Policy Tool for Past and Future Pandemics. JAMA Netw Open. 2024 Aug 1;7(8):e2426820. doi: 10.1001/jamanetworkopen.2024.26820. PMID: 39141392. [invited editorial]
- **78.** Ciarkowski CE, Imlay HN, Bryson-Cahn C, Chan JD, Hartlage W, Hersh AL, **Lynch JB**, Martinez-Paz N, Spivak ES, Hardin H, White AT, Wu C, Vaughn VM, Kassamali Escobar Z. Antimicrobial stewardship to reduce overtreatment of asymptomatic bacteriuria in critical access hospitals: measuring a quality improvement intervention. Infect Control Hosp Epidemiol. 2024 Nov 11:1-7. doi: 10.1017/ice.2024.171. PMID: 39523519. [original work]
- **79.** Mitaka H, Bryson-Cahn C, Estebane JO, Makarewicz VA, **Lynch JB**, Chan JD. Recognizing asymptomatic bacteriuria in the surveillance of catheter-associated urinary tract infections-beyond fever and positive urine culture. Antimicrob Steward Healthc Epidemiol. 2024 Nov 14;4(1):e207. doi: 10.1017/ash.2024.459. PMID: 39563928; PMCID: PMC11574584. [original work]
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b. MedEdPortal Publications

- 1. UW School of Medicine Invaders and Defenders Course Module: "Introduction to Microbiology". Teaching module composed of a slide deck, facilitator notes, and interactive session (2015).
- 2. UW School of Medicine Invaders and Defenders Course Module: "Infectious Disease Diagnosis and Decision Making, Empiric vs Directed Therapy". Teaching module composed of a slide deck, facilitator notes, and interactive session (2015).
- 3. "Orbital Cellulitis and ID Principles". RWJF Reimagining Medical Education. Teaching video as part of a 5 medical school collaborative to reinvent microbiology and immunology teaching for medical students. Link: https://www.youtube.com/watch?v=ibuEGwrbmrA
- 4. University of Washington Department of Occupational and Environmental Medicine online course, "Infection Prevention & Control on Farms", https://osha.washington.edu/professional-development/course/ipcfarms-020320, launch April 6th, 2020, Department of Environmental & Occupational Health Sciences.
- 5. "Adult Antimicrobial Renal Dosing Guideline 2016", Jain R, Chan JD, Pottinger P, **Lynch JB**. UW OCCAM, link: https://occam.uwmedicine.org/uw-occam-library/guidelines-library/adult-antimicrobial-renal-dosing-guidelines-2016/
- "Antimicrobial Prophylaxis for Open Fractures", Lynch JB. UW OCCAM, link: https://occam.uwmedicine.org/uw-occam-library/guidelines-library/antibiotics-for-open fractures/
- 7. "Facial and Mandibular Fracture Antimicrobial Prophylaxis Guideline", Lynch JB. UW OCCAM, link: https://occam.uwmedicine.org/uw-occam-library/algorithm-library/facial-and-mandibular-fracture-antimicrobial-prophylaxis-guideline/
- 8. "UW Medicine Antibiotic Reference Kit", Jain R, Chan JD, Pottinger P, **Lynch JB**. UW OCCAM, link: https://occam.uwmedicine.org/uw-medicine-antibiotic-reference-kit/
- 9. UW Tele-Antimicrobial Stewardship website: www.uwtasp.org, Martinez-Paz N, Chan JD, Bryson-Cahn C, Kassamali-Escobar Z, Lynch JB

c. Book Chapters

Pediatric Malaria, *Textbook of Clinical Pediatrics*, 2nd Edition, ed. Elzouki AY. Springer-Verlag, 2011.

d. Published Books, Videos, Software, etc.

UW Tele-Antimicrobial Stewardship Pacific Northwest Antimicrobial Use Guidebook, Martinez-Paz N, Chan JD, Bryson-Cahn C, Kassamali-Escobar Z, **Lynch JB**, Volumes 1 and 2. www.uwtasp.org

e. Other publications

Lynch JD, Huster K. In Triaging Coronavirus, Prioritize Vulnerable, Healthcare Workers. Seattle Times, March 12, 2020 [editorial]

f. Manuscripts Under Review

g. Abstracts

- Robertson MN, Mossman S, Lynch JB, Greenberg PD. SIV-specific Cytotoxic
 T-lymphocytes Induced by DNA Immunization. 12th World AIDS Conference Geneva June 28-July 3 (1998).
- 2. **Lynch JB**, Herz AM, Greenberg PD. *Oral Inoculation with HIV-2 Elicits a Gag-specific Cytotoxic T-cell Response in Juvenile but not Neonatal Macaques*. 12th World AIDS Conference Geneva June 28-July 3 (1998).
- 3. **Lynch JB**, Ohlen C, Mulvania T, Greenberg PD. *Enhancement of the Murine Immune Response to Vaccination using FLT-3 Ligand* (Oral Presentation). American Federation for Medical Research Western Regional Conference. Carmel, CA February 9-12 (2000).
- 4. **Lynch JB**, Handsfield HH, Golden MR. *Successful Referral of Hepatitis C Infected Persons Detected through Screening at a Public STD Clinic*. National STD Conference. San Diego, CA. March 4-March 7 (2002).
- 5. **Lynch JB**, Ndauti R, John-Stewart G, Richardson B, Overbaugh J. *Potent and Broad HIV-specific Neutralizing Antibodies in Infants Are Not Associated with Prevention of Mother to Infant HIV Transmission*. AIDS Vaccine 2009. Paris, France. October 19-22 (2009).
- Clemens EC, Chan, JC, Lynch JB, Dellit TH. Relationship between Vancomycin Minimum Inhibitory Concentration, Dosing Strategies and Outcomes in Methicillin-Resistant Staphylococcus aureus Bacteremia. Infectious Disease Society of America Conference. Vancouver, BC, Canada. October 20-24 (2010).
- 7. <u>Oral Abstract Presentation:</u> McNamara E, **Lynch JB**, Dellit TH. *Multifaceted Approach to Prevention and Management of Ventilator-Associated Pneumonia*. University Health Consortium Annual Conference 2011- LEAP: Lead, Excel, Achieve, Perform. Chicago, IL, USA. September 21-23 (2011).
- 8. Chan JD, McNamara E, Dellit T, Lynch JB. Active surveillance cultures of Methicillin-

- Resistant Staphylococcus aureus (MRSA) as a tool to predict MRSA ventilator associated pneumonia. Infectious Diseases Society of American Conference, Boston, MA, October 20-24, 2011.
- 9. Chan JD, McNamara E, Dellit T, **Lynch JB**. The Impact of an Infection Control Bundle on Ventilator Associated Pneumonia Pathogens in the Intensive Care Units. Infectious Diseases Society of American Conference, Boston, MA, October 20-24, 2011.
- 10. <u>Oral Abstract Presentation:</u> **Lynch JB**, Jain R, Dellit, T. *Antimicrobial Stewardship*. University Health Consortium Annual Conference, Sept 13-14, 2012.
- 11. **Lynch JB**, Whimbey E, McNamara E, Mertens K, Maher K, Dellit TH. *High Level Influenza Vaccination of Healthcare Workers using One-on-one Education*. Infectious Diseases Society of American Conference, Boston, MA, October 17-21, 2012.
- 12. Choudhuri J, **Lynch JB**, Dellit T. *Enhanced Surveillance and Improved Efficiency Using an Automated Surveillance System for Detection of Nosocomial Multidrug Resistant Organisms*. Infectious Diseases Society of American Conference, Boston, MA, October 17-21, 2012.
- 13. Weissman S, Curtis D, Drekonja D, Beekman S, Buckmaster BP, **Lynch JB**, Abbott A, Fang F, Polgreen PM. *CaseFinder: A flexible real-time online surveillance registry for infectious disease physicians to report cases of carbapenem-resistant* Enterobacteriacea(*CRE*). *International Society for Disease Surveillance Conference, San Diego, CA, December 4-5, 2012.*
- 14. Maher K, Whimbey E, McNamara E, Mertens K, Dellit TH, Lynch JB. *Vaccination of Healthcare Workers Without a Mandate*. Seattle Nursing Research Symposium, Seattle, WA, January 28th, 2013.
- 15.Choudhuri JA, Chan JD, Hafermann MJ, Fulton C, Melius E, Schreuder AB, McNamara E, Pergamit R, **Lynch JB**, Dellit TH. *Shared Hoppers: A novel risk factor for the transmission of* Clostridium difficile. ID Week 2013. San Francisco, CA. October 5th, 2013.
- 16. Oral Abstract Presentation: Dellit TH, Chan JD, Fulton C, Pergamit R, McNamara E, Kim L, Ellenbogen R, **Lynch JB.** Reduction in Clostridium difficile infections among neurosurgical patients through the discontinuation of antimicrobial prophylaxis for the duration that an external ventricular drain remains in place. ID Week 2013. San Francisco, CA. October

3rd, 2013.

- 17. Hafermann M, **Lynch** JB. *Peri-operative Antibiotics: A Risk Factor for Developing Clostridium difficile in the TSICU*. Society for Critical Care Medicine 43rd Critical Care Congress, San Francisco, 2014.
- 18. Chu H, Huang D, Martine R, Jerome K, Dellit T, **Lynch JB**, Pottinger P, Chan J, Jain R, Kuypers J, Englund J. *Impact of Rapid Influenza PCR Testing on Inpatient Clinical Outcomes*. IDWeek, Philadelphia, PA, 2014.
- 19. <u>Oral Abstract Presentation.</u> Beieler AB, Dellit TH, **Lynch JB**. *OPAT in a Homeless Population*. IDWeek, Philadelphia, PA, 2014.
- 20.Garland TN, Rosser JI, **Lynch JB**. *Rifampin and Miliary Tuberculosis: A Cautionary Tale*. American College of Physicians Washington Chapter 2014 Annual Meeting, Oct 9th, 2014, Seattle, WA.
- 21. Morcos M, Garland TN, Logerfo J, Baird GS, **Lynch JB.** *Crystals in Time May Come*. Society of General Internal Medicine 2015 Northwest Regional Meeting, Feb 6th, 2015, Portland, OR.
- 22. Nandita Mani, MD; **John B. Lynch, MD, MPH**; Jeannie D. Chan, PharmD, MPH. *Clinical Outcomes and Severity of Disease in Bl/NAP1/027 Clostridium difficile Infections*. Poster presentation, American College of Physicians Regional Chapter Meeting, November 2015.
- 23. Nandita Mani, MD; **John B. Lynch, MD, MPH**; Jeannie D. Chan, PharmD, MPH. *Clinical Outcomes and Severity of Disease in BI/NAP1/027 Clostridium difficile Infections Compared to Non-NAP1 Strains*. Poster presentation, American College of Physicians Regional Chapter Meeting, May 2016.
- 24. Zhou Y, Lewis L, McIntosh M, Fang F, Pergamit R, Dellit TH, **Lynch JB**. *Risk Factors for Clostridium Difficile Infection in Colonized ICU Patients*. ID Week 2017, San Diego, CA.
- 25. Zhou Y, Martinez-Paz N, **Lynch JB**, Pottinger P. *Using Tele-Antimicrobial Stewardship to Reach Rural Hospitals in Washington State*. IDWeek 2017, San Diego, CA.
- 26. Ekici S, Gustafson K, Boonyaratoanakornkit J, **Lynch JB**, Lewis L, Haglund M, Chu HY. *Risk Factors and Clinical Outcomes due to Respiratory Syncytial Virus Hospitalization in Adults*. ACP Conference 2017.

- 27. Haglund M, Lynch JB, Lewis L, Kuypers J, Chu HY. Molecular epidemiology of severe RSV disease in hospitalized adults in Seattle, Washington, USA. RSV Vaccine for the World Meeting 2017, Malaga, Spain.
- 28. Kvak S, Lynch JB, Pottinger PS, Martinez-Paz N, D'Angeli MA. "Tele-Antimicrobial Stewardship for Critical Access Hospitals, Council on State and Territorial Epidemiologists Annual Conference 2018, West Palm Beach, FL
- 29. Cheng CW, Cizik AM, Dagal AHC, Lewis L, Lynch JB, Bellabarba C, Bransford RJ, Zhou H. Body mass index and the risk of surgical site infection following posterior cervical instrumented fusion in both trauma and non-trauma patients, American Academy of Orthopedic Surgeons Conference 2018, St. Louis, MO
- 30. Meagher AD, Lind M, Senekjian L, Iwuchukwu C, Lynch JB, Cuschieri J, Robinson B. Ventilator Associated Events are Associated with Worse Outcomes in Trauma Patients, American Association for the Surgery of Trauma Conference 2018, San Diego, CA
- 31. Long D, Chan J, Bryson-Cahn C, Lynch JB. Epidemiology of Surgical Site Infection in Spinal Fusion Surgery and Patterns of Discordance with Surgical Antibiotic Prophylaxis: A Retrospective Case-Level Analysis, International Anesthesia Research Society 2019, Montreal, Canada
- 31. McIntosh M, Lynch JB, Bryson-Cahn C, Makarewicz V. Review of Healthcare-Associated Bloodstream Infections: Engaging Frontline Providers, UW Certificate in Patient Safety and Quality Program 2019.
- 32. Martinez-Paz N, Kassamali-Escobar Z, Bryson-Cahn C, Lynch JB. Tele-Antimicrobial Stewardship in Critical Access Hospitals in Washington State, National Rural Health Association's 42nd Annual Conference, Atlanta, GA 2019.

17. Talks and Presentations

2010	23 lectures
2011	31 lectures
2012	23 lectures
2013	20 lectures
2014	20 lectures
2015	9 lectures
2016	20 lectures
2017	14 lectures
2018	13 lectures
2019	22 lectures

2020	
Jan 17	"Opioid Use Disorder Treatment and the ID Physician", Infectious
	Diseases Society of America Clinical Fellow's Conference, Naples, FL
Feb 19	"The Novel Coronavirus and Pandemic Disease Preparedness", Panel
	Speaker, The UW MetaCenter for Pandemic Preparedness and Global
	Health Security, Seattle, WA
May 18	"Pandemic Response", Hospital Association of New York
Jun 3	"The Seattle Experience: Insights for New COVID-19 Challenges",
	America's Essential Hospitals webinar
Jun 16	"COVID-19 Lessons Learned for a System-Wide Approach", Sepsis
	Conference, Seattle, WA
Sep 17	"COVID-19 Update", Washington State Orthopedics Association
Oct 14	"COVID-19: Is There an End in Sight?", Next Generation Medicine Lecture
Nov 14	"COVID-19 Situation", The Mountaineers Board of Trustees
2020 Invited	Lectures (cancelled due to COVID-19)
Apr 14	(Nant Canavation Madiaina, Canavarius, Flaga 7th, What Van Nand ta
Api 14	"Next Generation Medicine: Coronavirus, Ebola, Zika: What You Need to
Арт 14	Know About Emerging Viral Diseases", Next Generation Medicine
Арі 14	
Summer	Know About Emerging Viral Diseases", Next Generation Medicine
·	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA
·	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker,
·	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker, Antimicrobial Resistance and Stewardship Conference, Aga Kahn
Summer	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker, Antimicrobial Resistance and Stewardship Conference, Aga Kahn University Medical Center, Nairobi, Kenya
Summer	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker, Antimicrobial Resistance and Stewardship Conference, Aga Kahn University Medical Center, Nairobi, Kenya "Healthcare System Response to Protect and Serve in the Age of COVID-
Summer Sep 15	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker, Antimicrobial Resistance and Stewardship Conference, Aga Kahn University Medical Center, Nairobi, Kenya "Healthcare System Response to Protect and Serve in the Age of COVID-
Summer Sep 15 2021	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker, Antimicrobial Resistance and Stewardship Conference, Aga Kahn University Medical Center, Nairobi, Kenya "Healthcare System Response to Protect and Serve in the Age of COVID- 19", UW EMS & Trauma Conference, Seattle, WA
Summer Sep 15 2021	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker, Antimicrobial Resistance and Stewardship Conference, Aga Kahn University Medical Center, Nairobi, Kenya "Healthcare System Response to Protect and Serve in the Age of COVID- 19", UW EMS & Trauma Conference, Seattle, WA "COVID-19 and the Healthcare System Response", Washington Thoracic
Summer Sep 15 2021	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker, Antimicrobial Resistance and Stewardship Conference, Aga Kahn University Medical Center, Nairobi, Kenya "Healthcare System Response to Protect and Serve in the Age of COVID- 19", UW EMS & Trauma Conference, Seattle, WA "COVID-19 and the Healthcare System Response", Washington Thoracic
Summer Sep 15 2021 Jan 9	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker, Antimicrobial Resistance and Stewardship Conference, Aga Kahn University Medical Center, Nairobi, Kenya "Healthcare System Response to Protect and Serve in the Age of COVID- 19", UW EMS & Trauma Conference, Seattle, WA "COVID-19 and the Healthcare System Response", Washington Thoracic Society
Summer Sep 15 2021 Jan 9	Know About Emerging Viral Diseases", Next Generation Medicine Lecture, UW School of Medicine, Spokane, WA "A Global Perspective on Antimicrobial Resistance", Keynote Speaker, Antimicrobial Resistance and Stewardship Conference, Aga Kahn University Medical Center, Nairobi, Kenya "Healthcare System Response to Protect and Serve in the Age of COVID- 19", UW EMS & Trauma Conference, Seattle, WA "COVID-19 and the Healthcare System Response", Washington Thoracic

18. Other Employment

n/a

19. Expert Depositions/Testimonies

	Date	Case	Total Invoiced (\$)	Action
	2022	City of Snoqualmie v. Snoqualmie Police Association (on behalf of Chad Ridout)	900	arbitration
	2022	Gutzler v. City of Snoqualmie	600	arbitration
	2022	City of Snoqualmie vs. Snoqualmie Police Association	2175	arbitration
	2022	Shannon Bean v. Alaska Airlines	600	arbitration
:	2022	O'Farrell v. Horizon Airlines	600	record review
	2022	Files v Sellen Construction	900	record review
	2022	IBEW Local 77 on behalf of Isaac Tenney v City of Seattle	1950	arbitration
	2023	David Petersen, et al. v. Snohomish Regional Fire and Rescue	1500	summary judgement
	2023	Wendy Thomaston v City of Seattle	300	resolved
	2023	King County Police Officers Guild and Puget Sound Police Managers Association v. King County IBEW Local Union No.77 on Behalf	5100	arbitration
	2023	of Kristine Huffaker v. Seattle City Light, City of Seattle	2250	arbitration

2023	Bellingham Police Guild v. City of Bellingham	1650	PERC hearing, expert testimony
2023	Teamsters Locals 117 & 174 (Consolidated) v. King County	2400	arbitration
2023	Eastside Fire and Rescue and IAFF 2878 v. City of Issaquah	2100	arbitration
2023	Local 763 on Behalf of Brian Renninger v. Puget Sound Clean Air Agency	900	arbitration
2023	Neigal-Britt v Port of Seattle	600	arbitration
2023	Alana McCoy v. Port of Seattle City of Seattle	1050	arbitration
2023	Dixson v. City of Issaquah	1500	arbitration
2023	IBEW Union No, 77 on Behalf of Wendy Thomaston v. Seattle City Light	300	arbitration
2023	David Body vs. City of Seattle, et al. USDC, Case No. 2:22-cv-01017-LK	900	expert testimony, mediated
2024	Fisher et al v Wash. Dept. of Financial Institutions	450	arbitration
2024	Jackson v King County	600	arbitration
2024	Slater v Behavioral Health Resources	600	arbitration
2024	Lance Dickson v Seattle City Light	1950	arbitration

2024 Efimoff v Port of Seattle 2400 deposition

EXHIBIT B



Morbidity and Mortality Weekly Report (*MMWR*)

Morbidity and Mortality Weekly Report (MMWR) Home



Use of Updated COVID-19 Vaccines 2023–2024 Formula for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States, September 2023

Weekly / October 20, 2023 / 72(42);1140–1146

On October 10, 2023, this report was posted online as an MMWR Early Release.

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View suggested citation

Summary

What is already known about this topic?

Since September 2022, bivalent mRNA COVID-19 vaccines have been recommended in the United States, but the variants these vaccines were designed to protect against are no longer circulating widely. In September and October 2023, the Food and Drug Administration approved and authorized updated 2023–2024 Formula monovalent XBB.1.5 component–containing COVID-19 vaccines, formulated to target current variants more closely, specifically Omicron variant XBB.1.5, for persons aged ≥6 months.

What is added by this report?

On September 12, 2023, the Advisory Committee on Immunization Practices recommended vaccination with updated COVID-19 vaccines for all persons aged ≥6 months.

What are the implications for public health practice?

The updated COVID-19 vaccines are meant to broaden vaccine-induced immunity and provide protection against the currently circulating SARS-CoV-2 XBB-sublineage variants including against severe COVID-19–associated illness and death.

Abstract

COVID-19 vaccines protect against severe COVID-19–associated outcomes, including hospitalization and death. As SARS-CoV-2 has evolved, and waning vaccine effectiveness has been noted, vaccine formulations and policies have been updated to provide continued protection against severe illness and death from COVID-19. Since September 2022, bivalent mRNA COVID-19 vaccines have been recommended in the United States, but the variants these vaccines protect against are no longer circulating widely. On September 11, 2023, the

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Metric Details

Tables

Table 1

Table 2

Article PDF A
Full Issue PDF

Food and Drug Administration (FDA) approved the updated (2023–2024 Formula) COVID-19 mRNA vaccines by Moderna and Pfizer-BioNTech for persons aged >12 years and authorized these vaccines for persons aged 6 months–11 years under

Emergency Use Authorization (EUA). On October 3, 2023, FDA authorized the updated COVID-19 vaccine by Novavax for use in persons aged ≥12 years under EUA. The updated COVID-19 vaccines include a monovalent XBB.1.5 component, which is meant to broaden vaccine-induced immunity and provide protection against currently circulating SARS-CoV-2 XBB-sublineage variants including against severe COVID-19–associated illness and death. On September 12, 2023, the Advisory Committee on Immunization Practices recommended vaccination with updated COVID-19 vaccines for all persons aged ≥6 months. These

recommendations will be reviewed as new evidence becomes available or new vaccines are approved and might be updated.

Top

Introduction

By the end of 2022, COVID-19 vaccines had prevented 18.5 million COVID-19 hospitalizations and 3.2 million COVID-19 deaths in the United States (1). As SARS-CoV-2 has evolved, and waning vaccine effectiveness (VE) has been observed, vaccine formulations and policies have been updated to provide continued protection against severe COVID-19-associated illness and death. On September 11, 2023, the Food and Drug Administration (FDA) authorized the updated (2023–2024 Formula) COVID-19 mRNA vaccines by Moderna and Pfizer-BioNTech for use in persons aged 6 months–11 years under Emergency Use Authorization (EUA) and approved the updated Moderna and Pfizer-BioNTech COVID-19 vaccines for persons aged ≥12 years (2). On October 3, 2023, FDA authorized the updated Novavax COVID-19 vaccine for use in persons aged ≥12 years under EUA (2). The updated COVID-19 vaccines include a monovalent XBB.1.5 component and are meant to broaden vaccine-induced immunity and provide increased protection (compared with protection from earlier vaccines that might have waned) against currently circulating SARS-CoV-2 XBB-sublineage variants, which, by September 2, 2023, accounted for >99% of sequenced SARS-CoV-2 specimens in the United States.* As of September 11, 2023, bivalent mRNA COVID-19 vaccines (based on the ancestral SARS-CoV-2 strain and BA.4/BA.5 variants) are no longer authorized for use in the United States, and as of October 3, 2023, original monovalent Novavax COVID-19 vaccines (based on the ancestral SARS-CoV-2 strain) are no longer authorized for use in the United States. On September 12, 2023, the Advisory Committee on Immunization Practices (ACIP) recommended vaccination with the updated COVID-19 vaccine for all persons aged ≥6 months. These recommendations will be reviewed as new evidence becomes available or new vaccines are approved and might be updated.

Top

Background

Although severe COVID-19 is now less prevalent in the United States than during previous years, it continues to cause significant morbidity and mortality in this country. Currently, older adults (aged \geq 65 years) and infants aged <6 months are at highest risk for COVID-19–associated hospitalization. During January 1–August 26, 2023, COVID-19–associated hospitalization rates among adults aged \geq 75 years were two to three times as high as those among the next youngest age group (adults aged 65–74 years). Rates among infants aged <6 months are similar to those among adults aged 65–74 years (*3*).

Nevertheless, persons aged 6 months–64 years, including those with no underlying medical conditions, remain at risk for severe COVID-19. Rates of COVID-19–associated hospitalization are currently lowest among children and adolescents aged 5–17 years. However, among persons in this age group who were hospitalized with COVID-19 during January–June 2023, 23% of those aged 5–11 years and 34% of those aged 12–17 years had no underlying medical conditions. During January 2022–June 2023, among children and adolescents aged ≤17 years who died during a COVID-19 hospitalization, 50% had no underlying condition. During January 1–July 22, 2023, a total of 28,140 persons, including 26 aged <1 year, 18 aged 1–4 years, 36 aged 5–19 years, 463 aged 15–44 years, 2,821 aged 45–64 years, and 24,776 aged ≥65 years, died from COVID-19, as evidenced by COVID-19 being listed as the underlying cause of death on the death certificate.[†]

Post–COVID-19 conditions contribute to COVID-19–related morbidity among all age groups. The prevalence of ongoing symptoms ≥3 months after COVID-19 illness ranged from <1% among persons aged <18 years to 5% among those aged 35–49 years. During June 7–19, 2023, approximately one in four adults with post–COVID-19 conditions reported significant activity limitations (*4*).

Members of racial and ethnic minority groups continue to be disproportionately affected by COVID-19–associated hospitalization (5). Higher prevalences of underlying conditions in some racial and ethnic minority populations might increase their risk for severe COVID-19–associated outcomes (6). As of May 10, 2023, only 17% of the U.S. population had received a bivalent COVID-19 vaccine dose, with lower coverage among some racial and ethnic minority populations, potentially driven by differences in vaccine access and acceptability (5, 7).

After declining throughout the spring and early summer of 2023, COVID-19–associated hospitalization rates began increasing in mid-July 2023. Further increases are anticipated during the fall and winter respiratory virus season (*5*).

Methods

Since June 2020, ACIP has convened 37 public meetings to review data relevant to the potential use of COVID-19 vaccines.§ The ACIP COVID-19 Vaccine Work Group, comprising experts in adult and pediatric medicine, obstetrics and gynecology, infectious diseases, vaccinology, vaccine safety, public health, and ethics, has met weekly to review COVID-19 surveillance data; evidence regarding immunogenicity, efficacy, effectiveness, and safety of COVID-19 vaccines; and implementation considerations. The Work Group conducted a systematic review of benefits and harms of vaccination, and used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology to assess the certainty of the evidence regarding benefits and harms associated with a bivalent vaccine administered in the United States during September 2022– April 2023. The Work Group selected this population, intervention, and pandemic period of high seroprevalence to identify evidence most applicable to what can be anticipated from this year's vaccine in the United States. The certainty of evidence was assessed separately for infants and children aged 6 months–11 years, and adolescents and adults aged ≥12 years based on the difference in recommended vaccine dosage for these two age groups. The Work Group also reviewed additional CDC data on VE and safety, as well as data on the updated vaccines provided by manufacturers (8–10). To assess the evidence for benefits and harms associated with COVID-19 vaccine use, and to guide deliberations, ACIP uses the Evidence to Recommendations (EtR) Framework.** Within this framework, ACIP considered the importance of COVID-19 as a public health problem, including during the Omicron XBB-lineage-predominant era (January 2023–September 2023), as well as issues of resource use, benefits and harms, patients' values, acceptability, feasibility, and equity related to vaccine use. ACIP evaluated data related to all vaccines for which updated 2023–2024 formulations were anticipated (i.e., Moderna, Novavax, and Pfizer-BioNTech).

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Vaccine Effectiveness and Safety

Published assessments of previous vaccine formulations' VE and safety were evaluated using GRADE. GRADE is used to assess the confidence (high, moderate, low, or very low) that the true effect lies close to that of the estimated effect. Evidence that includes only randomized controlled trials begins at high certainty, whereas evidence that includes observational data begins at low certainty.

Among adolescents and adults, benefits of bivalent vaccination were assessed using pooled observational VE data for three outcomes: medically attended COVID-19, $^{++}$ hospitalization attributed to COVID-19, and death attributed to COVID-19. Pooled VE against medically attended COVID-19 was 53% (95% CI = 50%–56%), and hospitalization attributed to COVID-19 was 48% (95% CI = 30%–61%). For both critical outcomes, the certainty assessment was low. Fooled VE against death attributed to COVID-19 was 61% (95% CI = 41%–74%), and the certainty assessment was very low because of serious concern for inconsistency. Among infants and children, insufficient observational data were identified for a systematic review of benefits, but benefits were indirectly inferred from adolescent and adult data. The certainty assessment was very low for all three outcomes because of serious concern for indirectness.

Studies from the Vaccine Safety Datalink (VSD), a postauthorization vaccine safety monitoring system, were used to assess rates of serious adverse events (i.e., myocarditis or pericarditis and anaphylaxis, which were the outcomes specified for GRADE) that have been associated with vaccination (myocarditis after receipt of COVID-19 vaccine has been reported primarily in adolescent and young adult males) (11), and the certainty assessment was low among adolescents and adults and very low among infants and children. Severe reactogenicity (grade ≥3*** local or systemic reactions) was assessed using pooled clinical trial data after any original monovalent primary series dose. Severe reactogenicity occurred more often in the vaccine than placebo study arms, and the certainty assessment for the clinical trial body of evidence was low because of very serious concern for indirectness** in both age groups. The GRADE evidence profile is available at www.cdc.gov/vaccines/acip/recs/grade/covid-19-2023-2024-Monovalent.html.

Additional, updated CDC VE data were also reviewed, including data showing patterns of waning bivalent vaccine–induced immunity against infection and COVID-19–associated hospitalization during a period with increased Omicron XBB sublineage circulation (*12*, *13*). During September 2022–August 2023, VE against hospitalization among adults aged ≥65 years without an immunocompromising condition waned from 67% (95% CI = 62%–71%) at 7–59 days postvaccination to 28% (95% CI = 18%–36%) at 60–119 days (*13*). VE of both the original monovalent and bivalent vaccines against critical outcomes (invasive mechanical ventilation, intensive care unit admission, or death) has remained more durable than VE against less severe outcomes among adults, including those with and without immunocompromising conditions (*12*, *14*). VE patterns were similar among children and adults, although available data were more limited in children (*13*, *15*). VE against emergency department and urgent care visits among persons aged 5–17 years ranged from 59%–63% by age group 7–59 days after a bivalent dose,

waning to 36%–47% by age group 60–119 days after a bivalent dose (13). VE has historically been lower and has waned more quickly among adults with immunocompromise than among immunocompetent adults, although bivalent VE trends are less clear (12,13).

Additional, updated data on COVID-19 vaccine safety from VSD were also reviewed. The risk for myocarditis or pericarditis after receipt of a bivalent vaccine dose is uncertain because myocarditis is a rare outcome, and bivalent vaccination coverage is relatively low, especially in adolescents and young adults. Myocarditis rates after booster doses in adolescent and young adult males are lower than rates after primary series vaccination, but estimates for monovalent booster and bivalent doses are limited by the lower numbers of doses administered in VSD in this group (16). A longer interval between doses has been associated with lower rates of myocarditis (17).

ACIP recommendations for the updated COVID-19 vaccines were also guided by data on immunogenicity provided by the vaccine manufacturers. Data from Moderna, Novavax, and Pfizer-BioNTech show that monovalent XBB component–containing COVID-19 vaccines increase the immune response against the currently circulating XBB-sublineage variants (*8–10*). The evidence used to guide EtR is available at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-2023-2024-Monovalent-etr.html.

Top

Cost Effectiveness

COVID-19 vaccination is a cost-effective intervention, particularly in adults aged \geq 65 years, among whom incidence is highest. For this age group, a dose of the vaccine is cost saving (at an assumed cost of \$120 per dose). Among adults aged 50–64 years, the incremental cost-effectiveness ratio of updated COVID-19 vaccines was estimated to be \$25,787 per quality-adjusted life year, with estimates in those aged \geq 50 years robust to input changes across plausible ranges (18). For adults aged 18–49 years, the incremental cost-effectiveness ratio for updated COVID-19 vaccines was estimated to be \$115,588 per quality-adjusted life year, although estimates in younger adults were more sensitive to changes in input, with higher VE or hospitalization rates increasing cost-effectiveness (18). Cost-effectiveness estimates are not yet available for pediatric populations (18).

Top

Recommendations for Use of 2023–2024 COVID-19 Vaccines in Persons Aged ≥6 Months

On September 12, 2023, ACIP recommended vaccination with the updated (2023–2024 Formula) COVID-19 vaccine for all persons aged ≥6 months. The recommendation is inclusive of FDA-licensed or authorized updated monovalent XBB component–containing COVID-19 vaccines (i.e., Moderna, Novavax and Pfizer-BioNTech updated COVID-19 vaccines), consistent with the FDA-licensed indication or EUA. The recommendation for children aged 6 months–11 years is an interim recommendation because the updated COVID-19 vaccines for this age group are currently authorized under EUA. In addition, the recommendation for the updated Novavax COVID-19 vaccine is an interim recommendation because the Novavax COVID-19 vaccine is currently authorized under EUA.

Infants and children aged 6 months–4 years are recommended to receive a multidose initial series (previously referred to as the primary series) and at least 1 updated mRNA COVID-19 vaccine dose depending on vaccination history as defined herein. Infants and children aged 6 months–4 years who are unvaccinated are recommended to receive either 2 updated Moderna COVID-19 vaccine doses or 3 updated Pfizer-BioNTech COVID-19 vaccine doses (Table 1). Infants and children aged 6 months–4 years who previously received original monovalent or bivalent mRNA vaccine doses are recommended to receive 1 or 2 homologous (i.e., from the same manufacturer) updated COVID-19 mRNA vaccine doses, depending on vaccine manufacturer and the number of previous vaccine doses received. Infants and children aged 6 months–4 years who completed the initial series with original monovalent or bivalent mRNA vaccine doses are recommended to receive 1 updated COVID-19 vaccine dose, at least 2 months after receipt of the last COVID-19 vaccine dose. Infants and children aged 6 months–4 years may receive either the updated Moderna or Pfizer-BioNTech COVID-19 vaccine; however, all doses administered to an infant or child in this age group should be from the same manufacturer.

For those receiving updated mRNA COVID-19 vaccines, persons aged ≥5 years without immunocompromise are recommended to receive 1 updated COVID-19 vaccine dose, irrespective of previous COVID-19 vaccination history (Table 2). For those receiving updated Novavax COVID-19 vaccines, persons ages ≥12 years without immunocompromise are recommended to receive 2 updated COVID-19 vaccine doses if previously unvaccinated and 1 updated dose if previously vaccinated with any COVID-19 vaccine. For those who have received previous COVID-19 vaccines, the updated vaccine should be administered ≥2 months after receipt of the most recent dose.

Recommendations for 2023–2024 COVID-19 Vaccines in Persons Aged ≥6 Months Who Are Moderately or Severely Immunocompromised

Unvaccinated persons aged 6 months–11 years who are moderately or severely immunocompromised are recommended to receive an initial vaccination series of 3 homologous updated (2023–2024 Formula) mRNA COVID-19 vaccine doses.

Unvaccinated persons aged ≥12 years who are moderately or severely immunocompromised can complete an initial vaccination series with 3 homologous doses of updated mRNA or 2 doses of updated Novavax COVID-19 vaccine. Persons aged ≥6 months who are moderately or severely immunocompromised and previously received 1 or 2 original monovalent or bivalent mRNA vaccine doses are recommended to receive 1 or 2 homologous updated COVID-19 vaccine doses, depending on the number of previous vaccine doses. Persons aged ≥6 months who are moderately or severely immunocompromised who previously received ≥3 original monovalent or bivalent mRNA vaccine doses are recommended to receive 1 updated COVID-19 vaccine dose. Persons aged ≥12 years who are moderately or severely immunocompromised and who previously received original Novavax COVID-19 vaccine or Janssen (Johnson & Johnson) COVID-19 vaccine, including those who also received original monovalent or bivalent mRNA COVID-19 vaccine doses, are recommended to receive 1 updated COVID-19 vaccine dose from any FDA-authorized or approved manufacturer.

Persons who are moderately or severely immunocompromised, have completed an initial series, and have received ≥1 updated COVID-19 vaccine dose, may receive additional updated COVID-19 vaccine doses, guided by the clinical judgment of a health care provider and personal preference and circumstances. Any further additional doses should be administered ≥2 months after the last COVID-19 vaccine dose. Additional clinical considerations, including detailed schedules and tables by age and vaccination history for those who are and are not moderately or severely immunocompromised, are available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

Implementation Considerations

COVID-19 vaccines are transitioning from federal procurement and distribution into the commercial marketplace during fall 2023. Under the Affordable Care Act (ACA), ACIP recommendations for routine immunization that have been adopted by CDC and are listed on CDC Immunization Schedules are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without cost-sharing requirements. The Coronavirus Aid, Relief, and Economic Security (CARES) Act expedited coverage for COVID-19 vaccines; since January 5, 2021, ACA-covered insurers must cover, without cost sharing, any COVID-19 vaccine FDA authorized under an EUA or FDA approved under a Biologics License Application immediately upon authorization or approval of the vaccine (19). Thus, for U.S. residents with applicable ACA commercial medical insurance coverage, COVID-19 vaccines will be covered immediately. In addition, COVID-19 vaccines are covered under Medicare Part B, and nearly all Medicaid beneficiaries can receive COVID-19 vaccines without cost-sharing. COVID-19 vaccines are also included in the Vaccines for Children Program,**** which provides vaccines to approximately one half of U.S. persons aged <19 years at no cost. The Bridge Access Program for COVID-19 Vaccines is a public-private partnership serving as a temporary measure to maintain access to COVID-19 vaccines for adults who are uninsured or underinsured, working through both public health clinics and participating retail pharmacies.** Before vaccination, providers should provide the EUA Fact Sheet, SSSS manufacturer's package insert, or other written materials regarding the vaccine being administered and counsel vaccine recipients about expected systemic and local adverse reactions (reactogenicity).

Reporting of Vaccine Adverse Events

Adverse events after vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting is encouraged for any clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by telephone at 1-800-822-7967.

Top

Top

Top

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Top

Top

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Top

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Top

- * https://covid.cdc.gov/covid-data-tracker/#variant-proportions
- † https://wonder.cdc.gov/mcd-icd10-provisional.html (Accessed September 7, 2023).
- § https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html (Accessed September 7, 2023).
- https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html
- ** https://www.cdc.gov/vaccines/acip/recs/grade/downloads/acip-evidence-recs-framework.pdf
- ** Medically attended COVID-19 was defined as an emergency department or urgent care visit.
- ^{§§} Evidence that includes observational data starts at low certainty.
- Among persons aged ≥12 years, based on events occurring in a 0–1 day risk interval after either dose of primary series vaccination, the estimated incidence of confirmed anaphylaxis among adolescents and adults was 4.8 (95% CI = 3.2–6.9) per million doses of Pfizer-BioNTech COVID-19 vaccine and 5.1 (95% CI = 3.3–7.4) per million doses of Moderna COVID-19 vaccine. Among persons aged 12–39 years, based on events occurring in 7-day risk interval after vaccination versus a comparison interval in vaccinated persons, rates of chart-reviewed myocarditis or pericarditis per one million doses, were as high as 188 (95% CI = 86.0–356.9) in males aged 16–17 years after a monovalent booster dose of Pfizer-BioNTech COVID-19 vaccine.
- *** Grade 3 or 4 reactogenicity is generally defined as reactions that prevent daily routine activity, require use of a pain reliever, or require an emergency department visit or hospitalization. Definitions used for each clinical trial are provided on CDC webpages. (https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html; https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/reactogenicity.html)

- Wery serious concern for indirectness was noted because the body of evidence did not include anyone who received an updated dose, was from an earlier period of the pandemic, and excluded persons with previous COVID-19 infection, pregnant or breastfeeding women, and persons who were immunocompromised.
- ACIP voted (13 to one) to recommend vaccination with 2023–2024 (monovalent, XBB-containing) COVID-19 vaccines as authorized under EUA or approved by Biologics License Application in persons aged ≥6 months.
- Apart from the administration of additional doses, the FDA EUA for Novavax COVID-19 vaccine does not provide for a specific vaccination schedule for persons who are moderately or severely immunocompromised.
- **** https://www.cdc.gov/vaccines/programs/vfc/index.html
- https://www.cdc.gov/vaccines/programs/bridge/index.html (Accessed September 7, 2023).
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Top

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TABLE 1. Recommended COVID-19 vaccination schedule for persons aged 6 months–4 years who are not moderately or severely immunocompromised,* by COVID-19 vaccination history — United States, September 2023

Top

Previous COVID-19 vaccination history (before updated mRNA vaccine) [†]	Updated mRNA vaccine	No. of updated mRNA vaccine doses indicated	Interval between doses	
Unvaccinated	Moderna	2	Dose 1 and dose 2: 4–8 wks	
	Pfizer- BioNTech	3	Dose 1 and dose 2: 3–8 wks Dose 2 and dose 3: ≥8 wks	
Received Moderna vaccine				
1 dose any Moderna	Moderna	1	4–8 wks after last dose	
≥2 doses any Moderna	Moderna	1	≥8 wks after last dose	
Received Pfizer-BioNTech vaccine				
1 dose any Pfizer-BioNTech	Pfizer- BioNTech	2	Dose 1: 3–8 wks after last dose Dose 1 and dose 2: ≥8 wks	

Case 2:24-cv-01673-TL Document 16 Filed 05/23/25 Page 90 of 166

Previous COVID-19 vaccination history (before updated mRNA vaccine) [†]	Updated mRNA vaccine	No. of updated mRNA vaccine doses indicated	Interval between doses
2 doses any Pfizer-BioNTech	Pfizer- BioNTech	1	≥8 wks after last dose
≥3 doses any Pfizer-BioNTech	Pfizer- BioNTech	1	≥8 wks after last dose

^{*} Additional clinical considerations, including detailed schedules and tables by age and vaccination history for those who are and are not moderately or severely immunocompromised, are available. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Top

TABLE 2. Recommended COVID-19 vaccination schedule for persons aged ≥5 years who are not moderately or severely immunocompromised,* by COVID-19 vaccination history — United States, September 2023

COVID-19 vaccination history before updated vaccine [†]	Updated vaccine	No. of updated doses indicated	Interval between doses
Unvaccinated	Moderna	1	_
	Pfizer- BioNTech	1	_
	Novavax (aged ≥12 yrs only)	2	Dose 1 and dose 2: 3–8 wks
Receipt of ≥1 COVID-19 vaccine dose, including Moderna, Pfizer-BioNTech, Novavax (aged ≥12 yrs only), or Janssen (Johnson & Johnson) (aged ≥18 yrs only)	Moderna	1	≥8 wks after last dose
	Pfizer- BioNTech	1	≥8 wks after last dose
	Novavax (aged ≥12 yrs only)	1	≥8 wks after last dose

^{*} Additional clinical considerations, including detailed schedules and tables by age and vaccination history for those who are and are not moderately or severely immunocompromised, are available. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Top

Suggested citation for this article: Regan JJ, Moulia DL, Link-Gelles R, et al. Use of Updated COVID-19 Vaccines 2023–2024 Formula for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States, September 2023. MMWR Morb Mortal Wkly Rep 2023;72:1140–1146. DOI: http://dx.doi.org/10.15585/mmwr.mm7242e1 ...

[†] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised

[†] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised

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Last Reviewed: October 19, 2023

EXHIBIT C

Español | Other Languages





Vaccine Recommendations and Guidelines of the ACIP

Vaccine Recommendations and Guidelines of the ACIP Home

COVID-19 ACIP Vaccine Recommendations

Advisory Committee on Immunization Practices (ACIP)

Published in Morbidity and Mortality Weekly Report (MMWR)

The Advisory Committee on Immunization Practices (ACIP) provides advice and guidance to the Director of the CDC regarding use of vaccines and related agents for control of vaccine-preventable diseases in the civilian population of the United States. Recommendations made by the ACIP are reviewed by the CDC Director and, if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR).

See Clinical Considerations for Use of COVID-19 Vaccines



CURRENT COVID-19 Vaccine Recommendations

- MMWR: October 20, 2023 / 72(42);1140–1146.
 Use of Updated COVID-19 Vaccines 2023–2024 Formula for Persons Aged ≥6 Months: Recommendations of the Advisory
 Committee on Immunization Practices United States, September 2023
- MMWR: June 16, 2023 / 72(24);657–662
 Interim Recommendations for Use of Bivalent mRNA COVID-19 Vaccines for Persons Aged ≥6 Months United States,
 April 2023
- MMWR: November 11, 2022/ 71(45); 1436-1441
 Interim Recommendations from the Advisory Committee on Immunization Practices for the Use of Bivalent Booster
 Doses of COVID-19 Vaccines United States, October 2022 | MMWR (cdc.gov)
 - See also:
 - ACIP Evidence to Recommendations (EtR) for Use of Bivalent COVID-19 Vaccine Booster Doses under an Emergency Use Authorization | CDC
 - ACIP Evidence to Recommendations (EtR) for Use of Novavax COVID-19 Vaccine Booster Dose for adults ages
 18 years and older under an Emergency Use Authorization | CDC
- MMWR: August 4, 2022/ 71(31); 988-992
 Interim Recommendation of the Advisory Committee on Immunization Practices for use of the Novavax COVID-19 vaccine in persons aged 18 years and older— United States, July 2022
 - See also:
 - Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Novavax COVID-19 Vaccine (cdc.gov)
 - ACIP Evidence to Recommendations for Use of Novavax COVID-19 Vaccine, Adjuvanted in adults ages 18 years and older under an Emergency Use Authorization (cdc.gov)
 - The Novavax COVID-19 Vaccine's Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events (cdc.gov)
- Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Moderna COVID-19 Vaccine for Children Aged 6–11 Years

- Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Moderna COVID-19 Vaccine for Persons Aged 12-17 Years
- ACIP Evidence to Recommendations for Use of Moderna COVID-19 Vaccine in Children Ages 6 11 years and Adolescents Ages 12 17 years under an Emergency Use Authorization
- MMWR; June 28, 2022/ 71(26)

Interim Recommendations of the Advisory Committee on Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID-19 Vaccines in Children Aged 6 Months–5 Years — United States, June 2022

- See also:
 - GRADE: Moderna COVID-19 Vaccine for Children Aged 6 Months-5 Years | CDC
 - GRADE: Pfizer-BioNTech COVID-19 Vaccine for Children Aged 6 Months-4 Years | CDC
 - ACIP Evidence to Recommendations for Use of Moderna COVID-19 Vaccine in Children Ages 6 Months 5 Years and Pfizer-BioNTech COVID-19 Vaccine in Children Ages 6 Months – 4 Years under an Emergency Use Authorization | CDC
 - Moderna COVID-19 Vaccine's Reactions and Adverse Events | CDC
 - Pfizer-BioNTech COVID-19 Vaccine Reactions & Adverse Events | CDC
- EtR Update for a Pfizer-BioNTech COVID-19 Booster in Children Ages 5-11 Years
- EtR Framework for a 2nd COVID-19 Booster Dose in Adults Ages 50 Years and Older and Immunocompromised Individuals
- *MMWR*; March 17, 2022; 71(11)

Use of Moderna COVID-19 Vaccine in Persons Aged ≥18 Years and Considerations for Extended Intervals for Administration of Primary Series Doses of mRNA COVID-19 Vaccines — United States, February 2022

- See also:
 - Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Moderna COVID-19
 Vaccine | CDC
 - ACIP Evidence to Recommendations for Use of Moderna COVID-19 Vaccine | CDC
- *MMWR*; January 21, 2022; 71

Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices – United States, December 2021

• *MMWR*; November 5, 2021;70

Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 2021 Print version [5 pages]

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 - Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer-BioNTech, Moderna, and Janssen COVID-19 booster doses
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- *MMWR*; September 24, 2021;70

Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥16 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, September 2021

Print version [5 pages]

- See also:
 - Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer-BioNTech COVID-19
 Vaccine
 - ACIP Evidence to Recommendations for Use of Pfizer-BioNTech COVID-19 Vaccine
- *MMWR*; August 13, 2021;70

Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices — United States, July 2021

Print version [6 pages]

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Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021

Print version [6 pages]

• MMWR; May 14, 2021;70

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021

Print version [4 pages]

- See also:
 - Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer-BioNTech COVID-19
 Vaccine for Persons Aged 12-15 Years
 - ACIP Evidence to Recommendations for Use of Pfizer-BioNTech COVID-19 Vaccine under an Emergency Use Authorization
 - Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19
 Vaccine
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Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021

- See also:
 - Risk-Benefit Analysis
- *MMWR*; March 2, 2021;70

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021

Print version [4 pages]

- See also:
 - ACIP Evidence to Recommendations for Use of Janssen COVID-19 Vaccine under an Emergency Use Authorization
 - Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Janssen COVID-19 Vaccine
 - Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Janssen COVID-19 Vaccine
- *MMWR*; December 22, 2020;69

The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020

Print version [5 pages]

- See also:
 - Evidence Table for COVID-19 Vaccines Allocation in Phases 1b and 1c of the Vaccination Program
- MMWR; December 20, 2020;69

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020

Print version [4 pages]

- See also:
 - Evidence to Recommendations
 - GRADE Evidence Tables
 - Interim Clinical Considerations
 - Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events
- *MMWR*; December 13, 2020;69

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020

Print version [3 pages]

- See also:
 - Evidence to Recommendations
 - GRADE Evidence Tables

Case 2:24-cv-01673-TL Document 16 Filed 05/23/25 Page 96 of 166

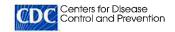
- Interim Clinical Considerations
- Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events
- Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites
- *MMWR*; December 3, 2020;69

The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

- See also:
 - Evidence Table

Last Reviewed: November 7, 2023

EXHIBIT D





The National Institute for Occupational Safety and Health (NIOSH)

The National Institute for Occupational Safety and Health (NIOSH) Home

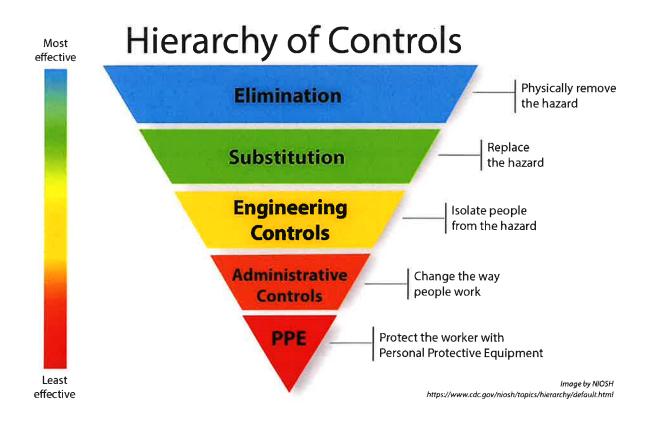


Hierarchy of Controls

Controlling exposures to hazards in the workplace is vital to protecting workers. The hierarchy of controls is a way of determining which actions will best control exposures. The hierarchy of controls has five levels of actions to reduce or remove hazards. The preferred order of action based on general effectiveness is:

- 1. Elimination
- 2. Substitution
- 3. Engineering controls
- 4. Administrative controls
- 5. Personal protective equipment (PPE)

Using this hierarchy can lower worker exposures and reduce risk of illness or injury.



Elimination removes the hazard at the source. This could include changing the work process to stop using a toxic chemical, heavy object, or sharp tool. It is the preferred solution to protect workers because no exposure can occur.

Substitution

Substitution is using a safer alternative to the source of the hazard. An example is using plant-based printing inks as a substitute for solvent-based inks.

When considering a substitute, it's important to compare the potential new risks of the substitute to the original risks. This review should consider how the substitute will combine with other agents in the workplace. Effective substitutes reduce the potential for harmful effects and do not create new risks.

Elimination and substitution can be the most difficult actions to adopt into an existing process. These methods are best used at the design or development stage of a work process, place, or tool. At the development stage, elimination and substitution may be the simplest and cheapest option. Another good opportunity to use elimination and substitution is when selecting new equipment or procedures. Prevention through Design is an approach to proactively include prevention when designing work equipment, tools, operations, and spaces.

Engineering Controls

Engineering controls reduce or prevent hazards from coming into contact with workers. Engineering controls can include modifying equipment or the workspace, using protective barriers, ventilation, and more. The NIOSH Engineering Controls Database has examples of published engineering control research findings.

The most effective engineering controls:

- are part of the original equipment design
- remove or block the hazard at the source before it comes into contact with the worker
- prevent users from modifying or interfering with the control
- · need minimal user input for the controls to work
- · operate correctly without interfering with the work process or making the work process more difficult

Engineering controls can cost more upfront than administrative controls or PPE. However, long-term operating costs tend to be lower, especially when protecting multiple workers. In addition, engineering controls can save money in other areas of the work process or facility operation.

Administrative Controls

Administrative controls establish work practices that reduce the duration, frequency, or intensity of exposure to hazards. This may include:

- · work process training
- job rotation
- · ensuring adequate rest breaks
- · limiting access to hazardous areas or machinery
- adjusting line speeds

PPE

PPE is equipment worn to minimize exposure to hazards. Examples of PPE include gloves, safety glasses, hearing protection, hard hats, and respirators. When employees use PPE, employers should implement a PPE program. While elements of the PPE program depend on the work process and the identified PPE, the program should address:

- · workplace hazards assessment
- PPE selection and use
- · inspection and replacement of damaged or worn-out PPE
- · employee training

Case 2:24-cv-01673-TL Document 16 Filed 05/23/25 Page 100 of 166

• program monitoring for continued effectiveness

Employers should not rely on PPE alone to control hazards when other effective control options are available. PPE can be effective, but only when workers use it correctly and consistently. PPE might seem to be less expensive than other controls, but can be costly over time. This is especially true when used for multiple workers on a daily basis.

When other control methods are unable to reduce the hazardous exposure to safe levels, employers must provide PPE.
This includes:

- · while other controls are under development
- · when other controls cannot sufficiently reduce the hazardous exposure
- when PPE is the only control option available

Administrative controls and PPE require significant and ongoing effort by workers and their supervisors. They are useful when employers are in the process of implementing other control methods from the hierarchy. Additionally, administrative controls and PPE are often applied to existing processes where hazards are not well controlled.

Training and evaluation can help ensure selected controls are successful. Employers should correctly train workers and supervisors on how to use controls. Workers and their supervisors should evaluate controls on a regular basis. Regular evaluation can check whether controls are effective in reducing workers' exposures and identify potential improvements.

Page last reviewed: August 11, 2022

Multiple Layers Improve Success

The Swiss Cheese Respiratory Pandemic Defense recognizes that no single intervention is perfect at preventing the spread of the coronavirus. Each intervention (layer) has holes.

Personal responsibilities **Shared** responsibilities Physical distance, Hand hygiene, If crowded. Ventilation, outdoors, Quarantine stay home if sick cough etiquette limit your time air filtration and isolation Masks Avoid touching Fast and sensitive Government messaging Vaccines your face testing and tracing and financial support

Source: Adapted from Ian M. Mackay (virologydownunder.com) and James T. Reason. Illustration by Rose Wong

Case 2:24-cv-01673-TL Document 16 Filed 05/23/25 Page 102 of 166

EXHIBIT E

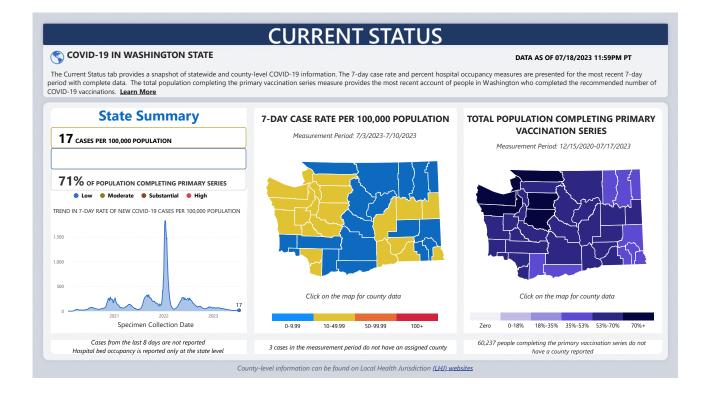


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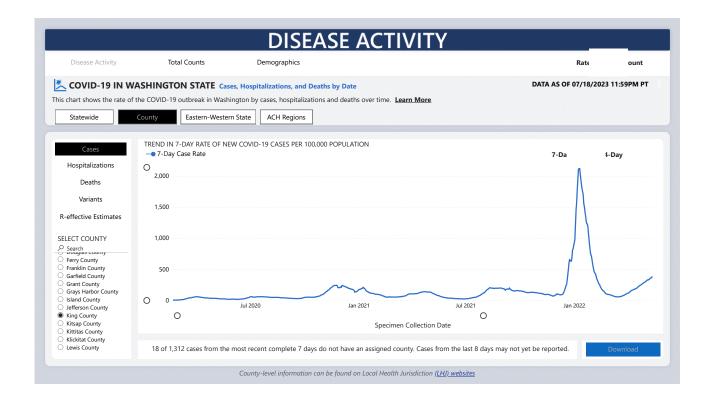
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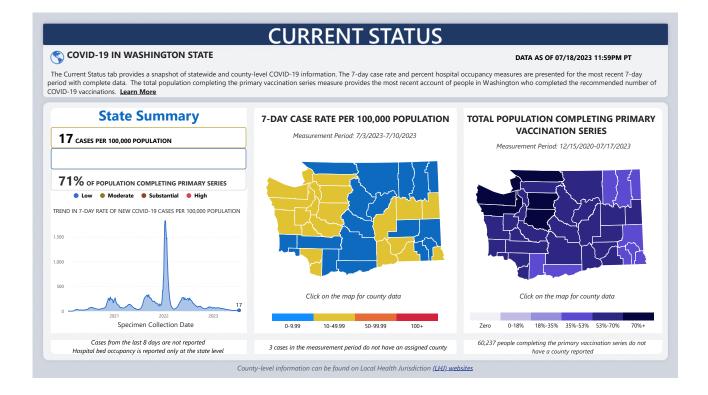


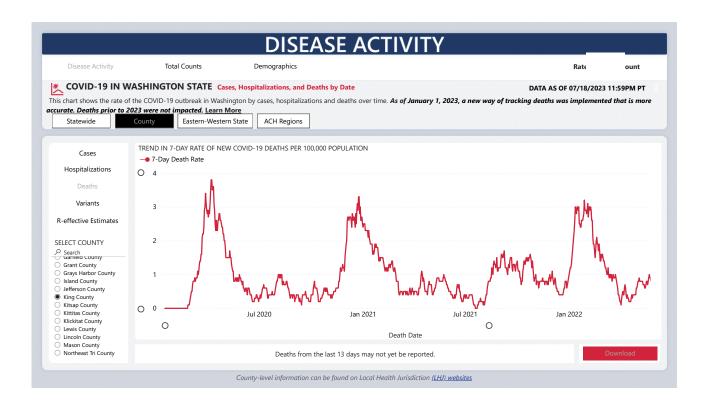
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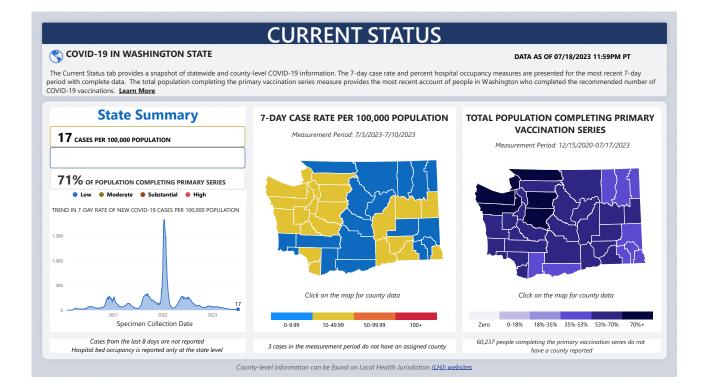


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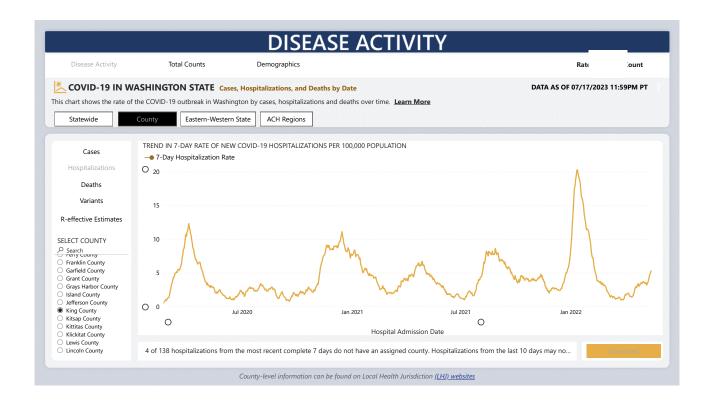
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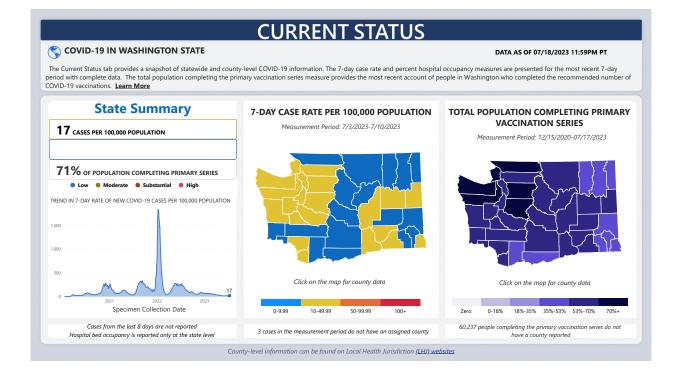


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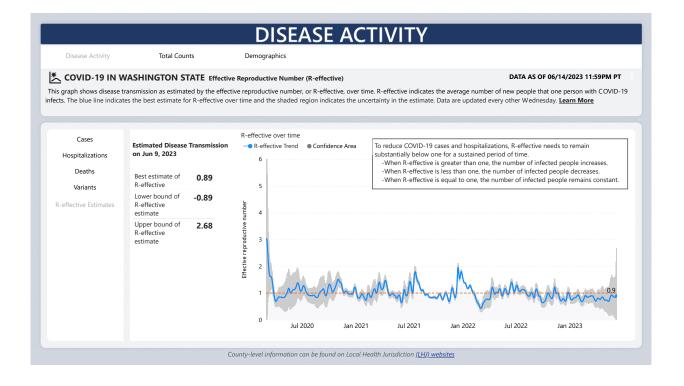


Case 2:24-cv-01673-TL Document 16 Filed 05/23/25 Page 110 of 166

Microsoft Power BI







Microsoft Power BI Pages



COVID-19 trends Updated weekly on Wednesday

On May 17, 2023, Washington State Department of Health implemented a new definition that changes how we track COVID-19 deaths on our dashboards and in published reports. The new definition for COVID-19 deaths affects deaths starting on January 1st, 2023, and results in some adjustments to death counts and rates. The new definition is based on <u>national standards for COVID-19 death</u> classification and will be applied moving forward.



This page shows data over time on the COVID-19 pandemic in King County, Washington since the beginning of the pandemic.

For up-to-date insights from Public Health – Seattle & King County, visit publichealthinsider.com.



Return to the COVID-19 data dashboards page or the COVID-19 main page



View the Current COVID-19 metrics page



Link/share this page at kingcounty.gov/covid/data/trends

Jump to:

Geography

Demographics

Outcomes by vaccination status

More Information

Overall trend

This figure shows the daily reported cases, hospitalizations, and deaths in King County since the beginning of the COVID-19 pandemic. Use the button below to switch between showing COVID-19 hospitalizations, reported cases, and deaths. Hover your cursor or tap part of the figure to see more details.

Case 2:24-cy-01673-TL Document 16 Filed 05/23/25 Page 112 of 166 Select a metric for the figure to display: Reported COVID-19 case rate Hospitalization rate due to COVID-19 Death rate from COVID-19 Select a date range for the figure to display: 1/1/20 2/16/22 Death rate from COVID-19 4 3 2 1 0 9/1/20 12/1/20 3/1/21 6/1/21 3/1/20

Updated: Wednesday, July 26, 2023

▲ Back to top

Geography

This map shows the rate of COVID-19 in each region of King County in weekly increments since the beginning of the COVID-19 pandemic. Use the button below to switch between showing COVID-19 hospitalizations and reported cases. Use the slider to select a date range.



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Geography

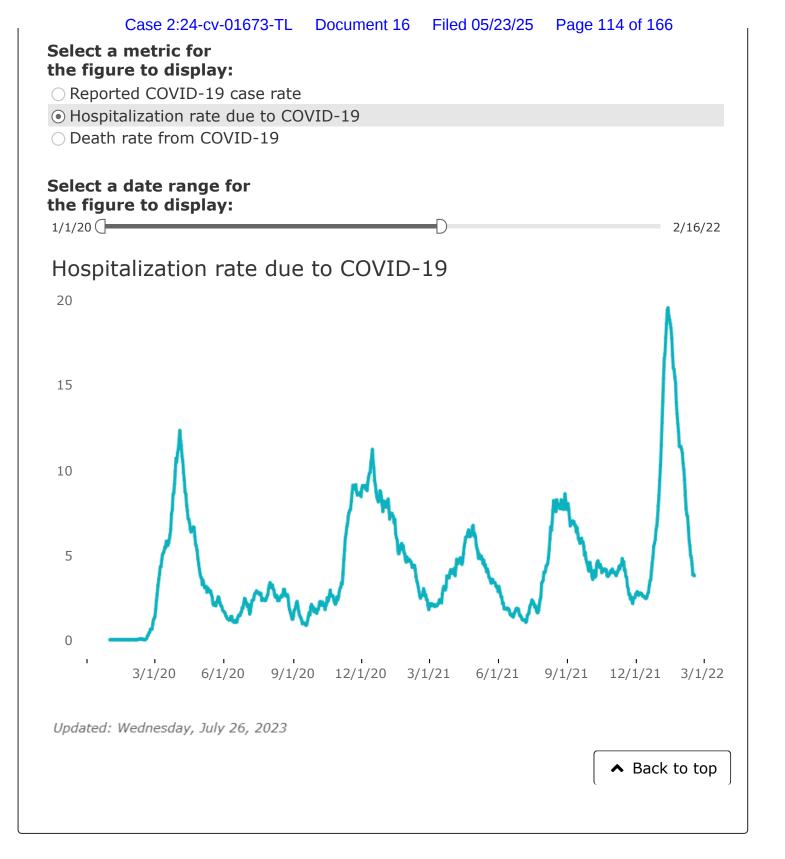
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Geography

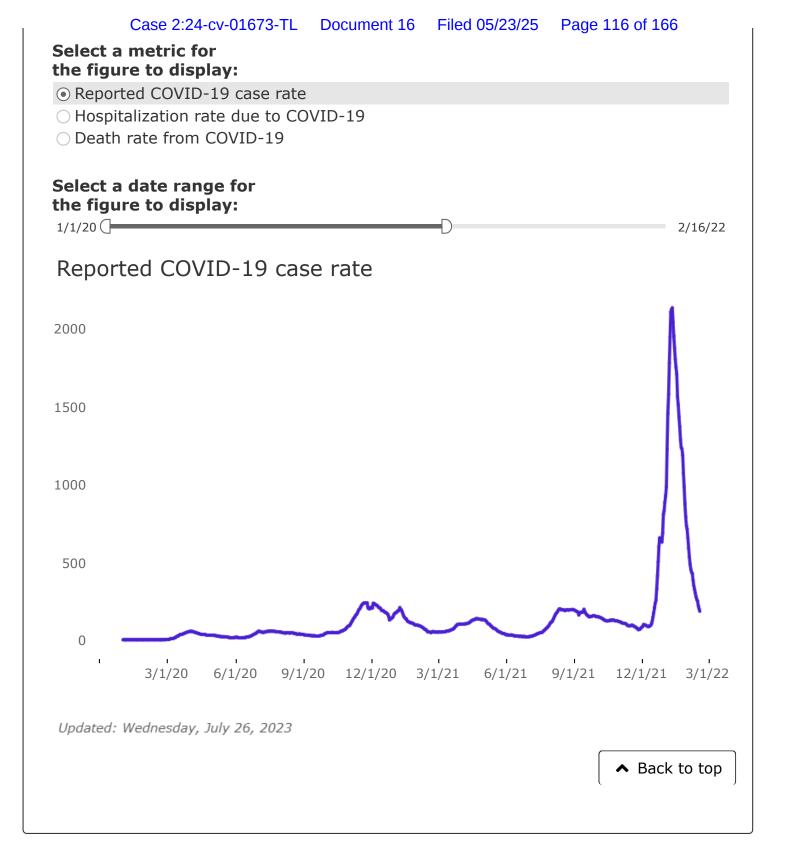
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More Information

Overall trend

This figure shows the daily reported cases, hospitalizations, and deaths in King County since the beginning of the COVID-19 pandemic. Use the button below to switch between showing COVID-19 hospitalizations, reported cases, and deaths. Hover your cursor or tap part of the figure to see more details.



Geography

This map shows the rate of COVID-19 in each region of King County in weekly increments since the beginning of the COVID-19 pandemic. Use the button below to switch between showing COVID-19 hospitalizations and reported cases. Use the slider to select a date range.

EXHIBIT F



COVID-19 Outcomes by Vaccination Status

2/1/2023
All data are through 1/26/2023

Open data notes

This dashboard describes COVID-19 outcomes among unvaccinated and vaccinated people in King County.

COVID-19 vaccines are highly effective at preventing serious illness, hospitalization, and death from COVID-19. However, since no vaccine is 100% protective, as more people are vaccinated we expect to see more cases in this group even when the vaccines continue to work well. These cases are often called "breakthrough" infections although the vast majority are not serious. For example, if everyone was vaccinated, 100% of cases would be among vaccinated people even though the risk for vaccinated people is much less than for the unvaccinated. So, the percent of cases that are vaccinated is not an accurate way to tell how well the vaccines are working.

A much better measure of how well the vaccines are working is the relative risk of COVID-19 infection for vaccinated and unvaccinated people. By comparing the risk (rate of disease) among vaccinated people and unvaccinated people of the same age, we see that the risk of catching COVID-19, of being hospitalized, or of dying is far higher for people who are not fully vaccinated relative to vaccinated people.

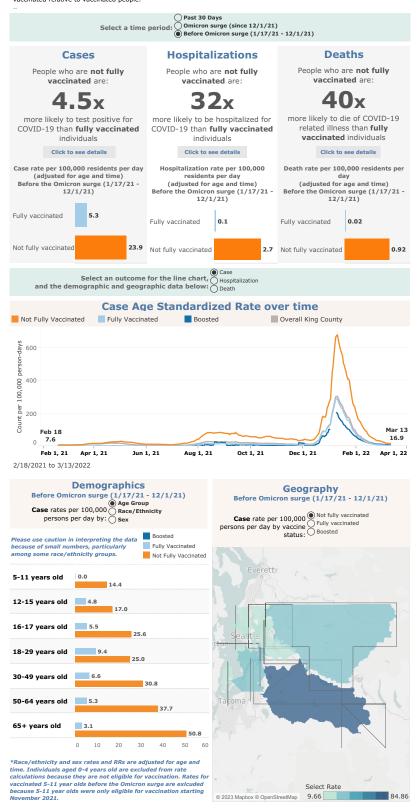


EXHIBIT G

Rebuttal Report of Dr. John Lynch Regarding: Dr. Risch's response to expert report provided by Dr.
John Lynch on January 21, 2025 in Dixson v. City of Issaquah, 2-24-cv-01673-TL.

Dated March 26, 2025.

John B. Lynch, MD, MPH, FIDSA

Introductory Comments Regarding Dr. Risch's Report:

- 1. At the time of the Governor's vaccine Proclamation and the City of Issaquah's vaccine mandate for its employees, ¹ there had been approximately 45 million cases of COVID-19 in the United States. ² In September 2021 the United States experienced a 4th wave of COVID-19. This wave caused the deaths of over 15,000 people per week. ³ To date, over 1.2 million Americans have died due to COVID-19, ⁴ and there are scientific data from multiple sources that indicated that this total is an undercount. ^{5,6}
- 2. The COVID-19 pandemic led to a massive loss of life, health, community, and severely impacted the communities across the globe, particularly in 2020, 2021, and 2022. COVID-19 continues to cause symptomatic infections leading to missed days of work and school, hospitalizations, and deaths.⁷
- 3. In 2021, the original strain of the virus that causes COVID-19 (SARS-COV-2), underwent serial evolutions leading to more infections and, especially with the delta and omicron variants, additional waves of hospitalizations and deaths.
- 4. In October 2021, there was considerable concern that additional waves of more infectious and more pathogenic were going to follow the delta wave. These waves, like the omicron wave in starting in late December 2021 and continuing through 2022, would lead to more suffering, death, and economic and social disruption in Washington State, the U.S. and the rest of the planet.
- 5. Aside from wide-spread, disruptive non-pharmaceutical interventions (NPIs) (e.g. requirements to stay at home, restrictions on crowded indoor settings like restaurants and some sporting events, and mandatory masking in places like grocery stores), COVID-19 vaccination was the only tool available to reduce human harm, suffering, and death.
- 6. Scientific data support the overwhelming, positive impact of the COVID-19 vaccines. This is not a point of controversy among global scientists, clinicians, and public health professionals. As stated in my expert report, COVID-19 vaccines prevented tens of

¹ See, e.g., https://governor.wa.gov/sites/default/files/proclamations/21-14.2%20-%20COVID-19%20Vax%20Washington%20Amendment%20(tmp).pdf

² See https://www.statista.com/statistics/1103185/cumulative-coronavirus-covid19-cases-number-us-by-day/

³ See https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00

⁴ See https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm

⁵ *See* https://www.bu.edu/sph/news/articles/2023/covid-19-deaths-in-the-us-continue-to-be-undercounted-research-shows-despite-claims-of-

 $overcounts/\#: \sim : text = Most\% 20 scientists\% 2C\% 20 however\% 2C\% 20 have\% 20 suggested, to\% 20 other\% 20 causes\% 20 of \% 20 death.$

⁶ See Stokes, A. C. et al. COVID-19 and excess mortality in the United States: A county-level analysis. *PLoS Med.* 18, e1003571 (2021).

⁷ See https://covid.cdc.gov/covid-data-tracker/#datatracker-home

- millions of deaths in the U.S. and globally. 8,9,10,11,12
- 7. For reasons that go beyond my areas of expertise, many Americans decided not to get vaccinated in 2021 despite well-documented effectiveness and safety data. Although no vaccine provides absolute protection from infection, hospitalization, and death, the fact the COVID-19 vaccines were not "perfect" was exploited by groups of people in the U.S. that have long-standing anti-vaccine stances. To many of these individuals and groups, there are no effective vaccines, including the COVID-19 vaccines.¹³
- 8. Misinformation (false information share by people who do not know that is the information is false) and disinformation (false information that is intentionally shared to mislead and to manipulate) about the COVID-19 vaccines increased rapidly soon after their release. We saw similar misinformation and disinformation regarding COVID-19 treatments, masking, and even the existence of the pandemic. The roots of this misinformation originated long before COVID-19 vaccines were available with the dissemination of false information regarding the safety and effectiveness of other vaccines like the measles-mumps-rubella (MMR) vaccine.
- 9. Many individuals involved with spreading COVID-19 vaccine misinformation and disinformation receive significant public recognition and in at least some cases compensation. As an example, Dr. Peter McCullough is a physician who was trained as a cardiologist and who has spread COVID-19 treatment and vaccine misinformation and disinformation, while also being paid as the chief medical officer of a supplement company that sells expensive, data-free, supplements that supposedly remove the spike protein from people who have been vaccinated. Despite having his American Board of Internal Medicine credentials revoked for spreading misinformation and having multiple COVID-19 papers retracted, he continues to receive significant recognition for his statements on COVID-19 treatment and vaccinations. Dr. Risch works for the same supplement company and has written papers on COVID-19 with Dr. McCullough (including one that has been retracted). 16,17

⁸ See Meslé, M. M. I. et al. Estimated number of lives directly saved by COVID-19 vaccination programmes in the WHO European Region from December, 2020, to March, 2023: a retrospective surveillance study. *Lancet Respir. Med.* 12, 714–727 (2024).

⁹ See Ikeokwu, A. E. et al. A Meta-Analysis To Ascertain the Effectiveness of COVID-19 Vaccines on Clinical Outcomes in Patients With COVID-19 Infection in North America. *Cureus* 15, e41053 (2023).

¹⁰ See Watson, O. J. et al. Global impact of the first year of COVID-19 vaccination: a mathematical modelling study. *Lancet Infect. Dis.* 22, 1293–1302 (2022).

¹¹ See Wu, N. et al. Long-term effectiveness of COVID-19 vaccines against infections, hospitalisations, and mortality in adults: findings from a rapid living systematic evidence synthesis and meta-analysis up to December, 2022. *Lancet Respir. Med.* 11, 439–452 (2023).

¹² See Zheng, C. et al. Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis. *Int. J. Infect. Dis.* 114, 252–260 (2022).

¹³ See Smith, T. C. & Reiss, D. R. Digging the rabbit hole, COVID-19 edition: anti-vaccine themes and the discourse around COVID-19. *Microbes Infect*. 22, 608–610 (2020).

¹⁴ See https://princetonlibrary.org/guides/misinformation-disinformation-malinformation-a-guide/

¹⁵ See Romer, D., Winneg, K. M., Jamieson, P. E., Brensinger, C. & Jamieson, K. H. Misinformation about vaccine safety and uptake of COVID-19 vaccines among adults and 5-11-year-olds in the United States. *Vaccine* 40, 6463–6470 (2022).

¹⁶ See https://www.twc.health/pages/dr-harvey-risch?srsltid=AfmBOoq7drvwOsVET8iqmSVvSj1KjgY5mkAelc8UYRKjuJuk1ME-wIUV

¹⁷ See https://retractiondatabase.org/RetractionSearch.aspx?AspxAutoDetectCookie

- 10. COVID-19 misinformation and disinformation are spread using anti-vaccine propaganda websites posing as scientific journals (ex. "Journal of the Academy of Public Health", "Science, Public Health Policy and the Law"), websites, social media, organizations (ex. Children's Health Defense), and books. 18 This network functions as an alternative universe that purveyors of misinformation and disinformation can use to support their aims. 19,20,21,22
- 11. Dr. Risch, despite having a long history of research in cancer risk epidemiology, repeatedly uses information from sources that are strongly associated with antivaccine propaganda. As examples, he cites "studies" from "Science, Public Health Policy and the Law" that cannot be found in PubMed (the globally accepted database for biomedical research literature), books by noted anti-vaccine authors like Naomi Wolf, Regina Watteel, and Ed Dowd, and a pre-print (non-peer reviewed) article claiming that vaccine data are an "illusion". ^{23,24,25} Further, Dr. McCullough, a well-known purveyor of COVID-19/vaccine misinformation, ²⁶ is a "clinical editor" on the "Science, Public Health Policy and the Law" website.
- 12. Employers had an ethical obligation to reduce suffering and harm due to COVID-19 in the state. Vaccine mandates are an effective tool to increase vaccinations and requiring COVID-19 vaccination for employees in 2021 was a reasonable decision given the very high level of concern that we were going to experience a more dangerous variant in late 2021 or 2022. Contrary to Dr. Risch's comments, the original

Support=1#?AspxAutoDetectCookieSupport%3d1%26auth%3dHarvey%2bA%2bRisch

<u>%252c%2bPeter%2bA</u>; *Notice of Recommended Disciplinary Sanction*, ABIM (Oct. 18, 2022), https://www.documentcloud.org/documents/23242430-abim-decision-on-mccullough/ (noting his COVID-19

statements, including many of the same opinions he seeks to provide here, were not "factual, scientifically grounded, or consensus driven").

²⁰ See Walter, D., Ophir, Y. & Ye, H. Conspiracies, misinformation and resistance to public health measures during COVID-19 in white nationalist online communication. *Vaccine* 41, 2868–2877 (2023).

²¹ See Jamieson, K. H., Johnson, K. B. & Cappola, A. R. Misinformation and the Vaccine Adverse Event Reporting System. *JAMA* 331, 1005–1006 (2024).

²² See Sule, S. et al. Communication of COVID-19 Misinformation on Social Media by Physicians in the US. *JAMA Netw. Open* 6, e2328928 (2023).

²³ See https://publichealthpolicyjournal.com/evaluating-data-integrity-and-reporting-challenges-in-publichealth-lessons-from-covid-19-data-collection-in-washington-state/

https://publichealthpolicyjournal.com/biontech-rna-based-covid-19-injections-contain-large-amounts-of-residual-dna-including-an-sv40-promoter-enhancer-sequence/

²⁴ See https://science.feedback.org/review/evidence-covid-19-vaccines-dont-increase-risk-death-contrary-claim-financier-edward-dowd/

²⁵ See https://science.feedback.org/?s=Naomi+wolf

²⁶ See e.g., Health Feedback, Reviews of Articles by Peter McCullough, https://healthfeedback.org/ authors/peter-mccullough; Dorit R. Reiss, Misinformation and Covid-19, 63 Santa Clara L. Rev. 147, 149-50 nn.3, 6-7 (2022) ("McCullough has become part of the anti-vaccine effort, speaking at anti-vaccine rallies and making statements against vaccines....[His proposed] treatments are not evidence-based and not recommended by expert authorities."); Retraction Watch Database, Peter A. McCullough, https://retractiondatabase.org/RetractionSearch.aspx#?auth%3dMcCullough

vaccines continued to significantly reduce a person's risk of COVID-19 infection, hospitalization, and death.

Specific Responses Regarding Dr. Risch's Report:

Specific Responses to Introduction Section of Dr. Risch's Report:

- 13. **Risch Rep. at pg. 1:** "Further, some of the materials cited in my report below were first published after Ms. Dixson's termination on or about February 16, 2022. I include such information generally as additional confirmation of earlier published materials that I discuss and from which I have derived conclusions." **Dr. Lynch's response:**
 - a. Although Dr. Risch states that he used "some" materials published after the plaintiff's termination, almost 30 of his sources are from 2022 or later. Even counting non-scientific sources, this is about 50% of all citations. He regularly uses information that was not available at the time of the City's implementation of the vaccine mandate.
 - b. In addition, Dr. Risch cites as authoritative articles, website articles (including his own articles), pre-prints, and books by known purveyors of information that have not been peer-reviewed or published in a research journal, including:
 - i. Risch HA. Hydroxychloroquine in Early Treatment of High-Risk COVID-19 Outpatients: Efficacy and Safety Evidence. Sixth version, updated June 17, 2021. https://earlycovidcare.org/wp-content/uploads/2021/09/Evidence-Brief-Risch-v6.pdf
 - ii. Neil M, Fenton N, McLachlan S. The extent and impact of vaccine status miscategorisation on covid-19 vaccine efficacy studies. medRxiv Preprint, March 25, 2024. https://www.medrxiv.org/content/10.1101/2024.03.09.24304015v2
 - iii. Knopik C. Evaluating Data Integrity and Reporting Challenges in Public Health: Lessons from COVID- 19 Data Collection in Washington State. Sci Publ Hlth Policy Law. 2024;5:2019-2024. Posted October 15, 2024. https://publichealthpolicyjournal.com/evaluating-data-integrity-and-reporting-challenges-in-public-health-lessons-from-covid-19-data-collection-in-washington-state/
 - iv. Gupta S. Have my Covid hypotheses held up? UnHerd, August 9, 2021. https://unherd.com/newsroom/sunetra-gupta-how-have-my-covid-hypotheses-held-up/
 - v. Kämmerer U, Schulz V, Steger K. BioNTech RNA-Based COVID-19 Injections Contain Large Amounts of Residual DNA Including An SV40 Promoter/Enhancer Sequence. Sci Publ Hlth Policy Law. 2024;5:2019-2024. https://publichealthpolicyjournal.com/biontech-rna-based-covid-19- injections-contain-large-amounts-of-residual-dna-including-an-sv40-promoter-enhancer-sequence
 - vi. Dowd E. "Cause Unknown": The Epidemic of Sudden Deaths in 2021 & 2022. New York, NY: Skyhorse Publishing, 2022. https://www.amazon.com/Cause-Epidemic-Sudden-Deaths-2021/dp/B0C6VMQJQD
 - vii. Watteel RN. Fisman's Fraud: The Rise of Canadian Hate Science. Ottawa, ON: Whisperwood Publishing, 2023.

https://www.amazon.com/Fismans-Fraud-Rise-Canadian-Science/dp/1988363241

Specific Responses to "Professional Training and Experience" Section of Dr. Risch's Report:

- 14. **Risch Rep. at pgs. 1-2:** "I am Professor Emeritus of Epidemiology at Yale School of Public Health, an elected Fellow of the American College of Epidemiology, and an elected member of the Connecticut Academy of Science and Engineering (on whose Covid-19 Management Recommendations Committee I served). I am a practicing epidemiologist with more than 40 years of research and teaching experience in the field." **Dr. Lynch's response:**
 - a. Although Dr. Risch completed medical school, he did not complete a residency in any medical specialty and has not provided patient care since attending medical school in 1976. He has not worked in public health or in public health policy development. He has no experience in clinical infectious diseases or vaccinations.
 - b. He has held no position in responding to the COVID-19 pandemic in any public health organization or health system.
- 15. **Risch Rep. at pg. 2:** "In May 2020, I published the seminal review paper on early treatment of high-risk Covid-19 out-patients in the American Journal of Epidemiology (https://doi.org/10.1093/aje/kwaa093), which has been downloaded almost 92,000 times and viewed by more than 168,000." **Dr. Lynch's response:**
 - a. There are no metrics to support Dr. Risch's claim to publishing "the seminal review paper" on this topic in May 2020. At least 2 letters of concern regarding this paper were published calling into question his analysis. ²⁷ Based on a Google Scholar search, this paper has been cited 136 times. I am a clinical infectious diseases physician and never heard about this paper and never used the suggested treatments.
 - b. In comparison, I published a review paper on mild or moderate COVID-19 (a similar topic as Dr. Risch's paper) with Drs. Raj Gandhi (Massachusetts General Hospital/Harvard Medical School) and Carlos Del Rio (Emory University School of Medicine) in April 2020 in the New England Journal of Medicine that has been cited 1897 times.²⁸ One can make a strong argument against Dr. Risch's claim.
 - c. In this paper, Dr. Risch claims that hydroxychloroquine and azithromycin should be used for the treatment of COVID-19. Subsequent studies did not find any benefit from these drugs and national guidelines recommended

²⁷ See Korman, T. M. RE: "EARLY OUTPATIENT TREATMENT OF SYMPTOMATIC, HIGH-RISK COVID-19 PATIENTS THAT SHOULD BE RAMPED UP IMMEDIATELY AS KEY TO THE PANDEMIC CRISIS." Am. J. Epidemiology 189, 1442–1443 (2020) and Peiffer-Smadja, N. & Costagliola, D. RE: "EARLY OUTPATIENT TREATMENT OF SYMPTOMATIC, HIGH-RISK COVID-19 PATIENTS THAT SHOULD BE RAMPED UP IMMEDIATELY AS KEY TO THE PANDEMIC CRISIS." Am. J. Epidemiology 189, 1443–1444 (2020).

²⁸ See https://scholar.google.com/scholar?hl=en&as_sdt=0%2C48&q=Lynch+jb+covid+nejm&btnG=

against their use.^{29,30}

- 16. **Risch Rep. at pg. 2:** "I have updated that analysis with a thorough review and metaanalysis through June 2021 (https://earlycovidcare.org/wp-content/uploads/2021/09/Evidence-Brief-Risch-v6.pdf)." **Dr. Lynch's response:**
 - a. This is an internet post that has had no peer-review and has not been published in any biomedical journal. Papers cited in this post in fact do not support Dr. Risch's recommendation for using hydroxychloroquine with or without azithromycin.³¹ For example, two papers highlight the potential dangers of using hydroxychloroquine.³² One paper has been retracted.³³ Multiple papers are preprints, meaning they have not been reviewed or published.
 - b. It would be remarkable that any medical professional would consider Dr. Risch's "thorough review and meta-analysis" as support for using hydroxychloroquine with or without azithromycin for COVID-19 in any population. Review of the cited studies indicates the exact opposite conclusion.
- 17. **Risch Rep. at pg. 2:** "I was senior author on the outpatient treatment clinical trial study in Brazil (https://doi.org/10.1016/j.tmaid.2020.101906), and have co-authored with Dr. Peter McCullough various papers on Covid-19, including two that explicate the now-standard understanding of early outpatient Covid-19 management (https://doi.org/10.1016/ j.amjmed.2020.07.003 and https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.264)." **Dr. Lynch's response:**
 - a. The paper that Dr. Risch was the senior author was an uncontrolled observational study that did not require a diagnosis of COVID-19 by testing and allowed for a variety of different medications and medication combinations. None of the results are valid.
 - b. More robust studies, including randomized controlled studies published in 2020, have shown that hydroxychloroquine has no impact on the course of COVID-19 in humans despite Dr. Risch's continued statements to the contrary.³⁴

²⁹ See Cavalcanti, A. B. et al. Hydroxychloroquine with or without Azithromycin in Mild-to-Moderate Covid-19. N. Engl. J. Med. 383, 2041–2052 (2020) and Elsawah, H. K., Elsokary, M. A., Elrazzaz, M. G. & Elshafie, A. H. Hydroxychloroquine for treatment of nonsevere COVID-19 patients: Systematic review and meta-analysis of controlled clinical trials. J. Méd. Virol. 93, 1265–1275 (2021).

³⁰ See https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/

³¹ See Skipper, C. P. et al. Hydroxychloroquine in Nonhospitalized Adults With Early COVID-19. Ann. Intern. Med. 173, M20-4207 (2020) and Mitjà, O. et al. Hydroxychloroquine for Early Treatment of Adults With Mild Coronavirus Disease 2019: A Randomized, Controlled Trial. Clin. Infect. Dis. 73, e4073–e4081 (2020) and Barnabas, R. V. et al. Hydroxychloroquine as Postexposure Prophylaxis to Prevent Severe Acute Respiratory Syndrome Coronavirus 2 Infection. Ann. Intern. Med. 174, M20-6519 (2020).

³² See Lane, J. C. E. et al. Risk of hydroxychloroquine alone and in combination with azithromycin in the treatment of rheumatoid arthritis: a multinational, retrospective study. *Lancet Rheumatol.* 2, e698–e711 (2020) and Mercuro, N. J. et al. Risk of QT Interval Prolongation Associated With Use of Hydroxychloroquine With or Without Concomitant Azithromycin Among Hospitalized Patients Testing Positive for Coronavirus Disease 2019 (COVID-19). *JAMA Cardiol.* 5, 1036–1041 (2020).

³³ See Retracted: Gautret, P. et al. Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial. *Int. J. Antimicrob. Agents* 56, 105949 (2020).

³⁴ See Skipper, C. P. et al. Hydroxychloroquine in Nonhospitalized Adults With Early COVID-19. Ann. Intern. Med. 173, M20-4207 (2020) and Mitjà, O. et al. Hydroxychloroquine for Early Treatment of Adults With Mild Coronavirus Disease 2019: A Randomized, Controlled Trial. Clin. Infect. Dis. 73, e4073–e4081 (2020) and

- c. The papers that Dr. Risch wrote with Dr. McCullough are the opposite of the "now-standard understanding of early outpatient Covid-19 management". One citation is a letter to a journal, and another is an opinion article without any study data. Neither of these papers are cited for support in either the Infectious Diseases Society of American or the National Institutes of Health COVID-19 treatment guidelines.³⁵ The third link (rcm.impress.com....) does not work.
- d. Dr. McCullough is a known purveyor of COVID-19 misinformation. His American Board of Internal Medicine certifications were revoked for this reason, and he has had multiple COVID-19 papers retracted due to concerns about the methods and data used.
- 18. **Risch Rep. at pg. 2:** "In other respects, while the majority of my career research has focused on various types of cancers as outcomes of interest, that work has involved the examination of a host of potential causal factors, including medications and infectious diseases. I was prepared to do research involving these risk factors by my medical education which included arguably one-quarter of its coursework on infectious diseases, and another similar amount on biochemistry, molecular and cellular biology, pharmacology, immunology and pathology." **Dr. Lynch's response:**
 - a. As stated above, Dr. Risch is not an infectious diseases researcher, a clinician, or a public health professional. He wrote that he is prepared to do research in the areas of COVID-19, COVID-19 therapeutics, vaccines, and operational mitigations based on microbiology classes he took in the 1970s as a medical student. As a person who also went to medical school, I know that the level of microbiology and infectious diseases training in medical school is rudimentary at best and does not prepare a person to do clinical work, research, or response work.
 - b. Dr. Risch has never worked in occupational health nor has worked on or led a workplace vaccination program (per his CV).
 - c. Twenty of Dr. Risch's Yale colleagues signed a statement that "voiced concern over Risch's ardent advocacy of hydroxychloroquine". 36

Specific Responses to "Background: Public Health Management of the Covid-19 Pandemic" Section of Dr. Risch's Report:

19. **Risch Rep. at pg. 3:** "However, by the end of 2023, <u>CDC reported</u> (see figure next page) that cumulatively more than 87% of Americans had been infected with Covid-19 in spite of the massive, prolonged and booster-repeated national vaccination campaign. This inevitable spread was predicted in summer 2021 (see calculations in next paragraph). My point is that by prioritizing numbers of infections rather than the more serious but less common consequences of both infections and policy harms, this and other vaccine mandate proclamation policies failed their main terms of reference in that more than 87% of Americans eventually became infected anyway." **Dr.**

Cavalcanti, A. B. *et al.* Hydroxychloroquine with or without Azithromycin in Mild-to-Moderate Covid-19. *N. Engl. J. Med.* 383, 2041–2052 (2020).

³⁵ See https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/ and https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/ and https://www.ncbi.nlm.nih.gov/books/NBK570371/pdf/Bookshelf NBK570371.pdf

³⁶ See https://yaledailynews.com/blog/2020/08/16/ysph-professor-criticized-for-promoting-unproven-drug-to-treat-covid-19/

Lynch's response:

- a. The reference to the CDC document is from 2024 and presents data from quarter 1 of 2022 through quarter 4 of 2023. None of these data are from the implementation of the Proclamation or the City's vaccine mandate and were not available during that time. As of the middle of October 2021, just over 50% of Americans had received 2 doses of the vaccines. Conversely, nearly 50% of people were not fully vaccinated. In the CDC chart, about 50% of people in the cohort (blood donors) had evidence of past infection, which is not surprising given the number of unvaccinated people and the rise of the omicron variants during that time.
- b. The number of cases was not prioritized over other tracking metrics. Cases, hospitalizations, and deaths were tracked throughout the pandemic.
- c. Public health tracking of cases was extremely helpful for healthcare facilities, businesses, schools, policy makers and many others as a rise in cases predicted an increase in clinic visits, emergency department visits, admissions to hospitals, and deaths.
- d. The main drivers of pandemic after the roll-out of the vaccines was the extremely large number of people who did not get vaccinated, which increased the overall burden of diseases in the community and exposure to both unvaccinated and vaccinated people, and the introduction of the omicron variants in late 2021 and early 2022 that led to some immune escape. Fortunately, updated vaccines became available.
- e. What proportion of the U.S. population was going to be infected by the end of 2023 was unknown at the time of the Proclamation and the City's vaccine mandate.

Specific Responses to "Background: Post-infection Natural Immunity vs Vaccine Immunity Against Covid-19" Section of Dr. Risch's Report

- 20. **Risch Rep. at pg. 4:** "Most Covid-19 vaccination mandates, including the one issued by the City of Issaquah, have ignored the role that post-infection "natural" immunity plays in helping to control the adverse consequences of the pandemic." **Dr. Lynch's response:**
 - a. Vaccination provided substantial protection against infection, hospitalization, and death due to COVID-19. Vaccination of people with a history of COVID-19 provided the highest level of protection. Assessing a person's history of infection did not change public health recommendations regarding vaccination.
- 21. **Risch Rep. at pg. 4:** "With an organism of reproduction transmission R0 of approximately 3 (original strain) or more than 6 (Delta, and later, Omicron also) (Kollmeyer, 2021; Gallagher, 2021), sustained natural and vaccine effectiveness against transmission would have had to remove infection susceptibility from some 83% or more people in the population (i.e., 1 1/6)—e.g., for vaccination to have indefinitely lasting efficacy against transmission above 90% in a population more than 90% vaccinated—in order to terminate the spread, and achieving these degrees of both vaccination uptake and vaccine performance were unrealistic during the pandemic."

Dr. Lynch's response:

a. I am unclear why Dr. Risch states that we could not achieve a higher level of vaccine uptake in the United States. When the R_0 was lower, we could have

- significantly impacted the course of the pandemic. Instead, many individuals decided not to get vaccinated despite the data and the risk of infection.
- b. The analysis of transmission in totally immune or mixed populations is approached differently. For example, for a virus with an R₀ of 3, one infected person would infect, on average, 3 other, non-immune people. This outcome is very different when there is high level population immunity. For example, measles has one of the highest known R0 (between 12 and 18) but outbreaks due to measles in the U.S. are usually limited by the fact that most people are fully vaccinated. A more appropriate epidemiological term is the effective reproduction number or R_t which incorporates the proportion of people who have immunity to infection.³⁷
- c. The goal of vaccination is to reduce harm. This reduction accrues to the individual by reducing the risk of infection, long-COVID, lost time (school, work, etc), healthcare utilization, hospitalization, and death. Vaccination also reduces harm to the public by increasing immunity and slowing transmission.
- d. An analysis by the Brown University School of Public Health showed that if every eligible person was vaccinated in 2021, there would have been ~320,000 fewer deaths in the U.S. between January 2021 and April 2022.³⁸ That is nearly one-half of the deaths that occurred after vaccines became available.
- e. Every legal and ethical effort in increase COVID-19 vaccination was appropriate at the time of the City's vaccine mandate.
- 22. **Risch Rep. at pg. 4:** "Thus, it was inevitable and apparent by the arrival of the Delta strain in summer 2021 that the overwhelming majority of the population would eventually get infected with the virus at some point." **Dr. Lynch's response:**
 - a. Slowing the spread of COVID-19 was an important goal of all mitigations, including vaccinations. The fact that there were breakthrough infections does not negate this fact or the impact of the COVID-19 vaccines.
- 23. **Risch Rep. at pg. 4:** "While post-infection population herd immunity likely slowed the spread, neither it nor vaccine immunity were ever able to control the spread of the infection overall." **Dr. Lynch's response:**
 - a. Dr. Risch appears to admit that infection-mediated immunity is not sufficiently protective against COVID-19.
 - b. Efforts to maximally increase vaccination were incredibly important given the experience with the delta wave and concerns about future variants, including ones that could be more dangerous.
 - c. It is unambiguous that COVID-19 vaccination prevented countless infections, 10 million hospitalizations, and ~1 million deaths by the end of 2021 (Lynch expert report ¶53). If more people were vaccinated in early 2021, ~50% of the deaths that occurred by the spring of 2022 could have been prevented.³⁹
- 24. **Risch Rep. at pg. 4:** "Nevertheless, that fact is not of policy consequence, because case count is not and should not have been the main public health priority—spread per se is not the issue—rather, the consequences of the spread and the negative consequences of the policies should have been the priorities." **Dr. Lynch's response:**
 - a. Based on the materials that I reviewed, I am not aware of any statement by the

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³⁷ See Yadav, A. K., Kumar, S., Singh, G. & Kansara, N. K. Demystifying R Naught: Understanding What Does it Hide? *Indian J. Community Med.: Off. Publ. Indian Assoc. Prev. Soc. Med.* 46, 7–14 (2021).

³⁸ See https://globalepidemics.org/vaccinations/

³⁹ *Ibid*

City of Issaquah that cases counts were the main public health policy objective. Case counts were one of multiple public health metrics that public health jurisdictions, health systems, and governments used to monitor the course of the pandemic. Other metrics included hospitalizations and deaths due to COVID-19.

- 25. **Risch Rep. at pg. 4:** "Belatedly, <u>CDC</u> in August 2022 came to a similar conclusion: 'public health efforts [should] minimize the individual and societal health impacts of COVID-19 by focusing on sustainable measures to further reduce medically significant illness'." **Dr. Lynch's response:**
 - a. The cited CDC document is from August 2022 and reflects a status of the pandemic and circulating omicron variants that was unknown at the time of the vaccine mandate.
 - b. Dr. Risch provides a very superficial perspective on the cited CDC document. In that document, under the section titled "Vaccines and Therapeutics to Reduce Medically Significant Disease" the authors wrote: "COVID-19 vaccines are highly protective against severe illness and death and provide a lesser degree of protection against asymptomatic and mild infection." 40
- 26. **Risch Rep. at pg. 4:** "Mao and colleagues (Mao et al., 2022) carried out a meta-analysis of studies of reinfection risks in patients previously infected with SARS-CoV-2. This paper was published on-line December 13, 2021, but the 19 studies included in its meta-analysis had already been published through May 1, 2021. In that meta-analysis, among the followed cohorts totaling 325,225 people who had had Covid-19, 1,096 reinfections were noted, for a risk of 0.34% in the pre-Delta Covid-19 period. Three more studies of reinfections were published in April-June 2021 (Letizia et al., 2021; Vitale et al., 2021; and Abo-Leyah et al., 2021), one in November (Kojima et al., 2021) and a fifth in December (Chemaitelly et al., 2021), bringing the total reinfection risk estimate to 1,242/372,368 = 0.33%, about 1 in 300 post-infection individuals. Durations of follow-up in these studies were all greater than 90 days save one study, and a number of studies followed subjects for 4-6 months or more." **Dr. Lynch's response:**
 - a. At the time of the City's vaccine mandate, public health organizations across the planet, including the CDC, continued to recommend that all eligible people get vaccinated regardless of prior COVID-19 infection history.
 - b. A history of COVID-19 infection is not a contraindication to COVID-19 vaccination. In fact, the combination of prior infection and vaccination, also known as hybrid immunity, appears to provide the highest level of protection.
 - c. As seen with vaccine-induced immunity, the immune response to infection fades over time, leaving the individual susceptible to infection. The only possibilities at that time are to get vaccinated (boosted) or get infected again, with all the attendant risks.
 - d. Regarding the papers available in 2021 that Dr. Risch cites:
 - i. The paper by Letizia and colleagues wrote the following conclusion: "Seropositive young adults had about one-fifth the risk of subsequent infection compared with seronegative individuals. Although antibodies induced by initial infection are largely protective, they do not guarantee effective SARS-CoV-2 neutralisation activity or immunity against subsequent infection. These findings might be relevant for optimisation

⁴⁰ See https://www.cdc.gov/mmwr/volumes/71/wr/mm7133e1.htm

- of mass vaccination strategies."41
- ii. The study described by Vitale and colleagues included this statement in the discussion: "However, the observation ended before SARS-CoV-2 variants began to spread, and it is unknown how well natural immunity to the wild-type virus will protect against variants." ⁴²
- iii. The third paper in this section is by Abo-Layed and colleagues. Critically, this study was performed in 2020, prior to the emergence of variants. While infection mediated immunity was associated with a lower risk of infection, it was unknown if and how this would apply in the variant-phase of the pandemic.
- 27. **Risch Rep. at pg. 4:** "Confirming this, a later meta-analysis of reinfection studies (COVID-19 Forecasting Team, 2023) estimated that protection against ancestral, Alpha, and Delta reinfection averaged about 85% and lasted at this level for some nine months before starting to wane." **Dr. Lynch's response:**
 - a. These data were not available at the time of the City's vaccine mandate. The data also demonstrate that the immune response after infection does wane, leaving the individual susceptible again.
- 28. **Risch Rep. at pg. 5:** "I am not arguing that people should have sought to be infected in order to obtain post-infection immunity, but given that it was clear by mid-2021 that almost everyone would eventually get infected at some point, recognition of this fact should have played a practical role in the management of the pandemic." **Dr. Lynch's response:**
 - a. What then is Dr. Risch is advocating for? The only alternative to vaccination was to allow infections to move through the population without any control.
- 29. **Risch Rep. at pg. 5:** The paragraph starting with "Head-to-head comparisons of post-infection (reinfection) vs post-vaccination (breakthrough)..." **Dr. Lynch's response:**
 - a. Multiple studies cited by Dr. Risch are from 2022 and 2023 (Leon, et al, 2022, Gazit, et al, 2022, and Bozio, et al, 2023). None of these were available in the fall of 2021.
 - b. Dr. Risch cites a systemic review by Shenai and colleagues from October 2021 to suggest an increased risk of infection in vaccinated people compared to people with a prior infection. Only one of the included studies could possibly support this, written by Satwick, et al, in 2021.⁴³,⁴⁴ That latter paper compared outcomes in people vaccinated with the ChAdOx1 (Oxford/AstraZeneca) vaccine. This vaccine was not ever used in the United States so those data are irrelevant to this discussion.
 - c. None of the authors of on the Shenai publication have published any epidemiological papers, on COVID-19 or any other infectious disease, before or after this single one. The senior author on the Shenai paper is Dr. Hooman

⁴¹ See Letizia, A. G. et al. SARS-CoV-2 seropositivity and subsequent infection risk in healthy young adults: a prospective cohort study. *Lancet Respir. Med.* 9, 712–720 (2021).

⁴² See Vitale, J. et al. Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy. *JAMA Intern. Med.* 181, 1407–1408 (2021).

⁴³ See Shenai, M. B., Rahme, R. & Noorchashm, H. Equivalency of Protection From Natural Immunity in COVID-19 Recovered Versus Fully Vaccinated Persons: A Systematic Review and Pooled Analysis. *Cureus* 13, e19102 (2021).

⁴⁴ See Satwik, R., Satwik, A., Katoch, S. & Saluja, S. ChAdOx1 nCoV-19 effectiveness during an unprecedented surge in SARS COV-2 infections. *Eur. J. Intern. Med.* 93, 112–113 (2021).

- Noorchashm. Dr. Norchashm has publicly claimed, without any data, that vaccinating people who have been infected is potentially harmful potentially creating a concern for a conflict in interpretation of other studies.⁴⁵
- d. Regarding the cited paper by Leon, et al (2022), the authors concluded, "Although the epidemiology of COVID-19 might change as new variants emerge, vaccination remains the safest strategy for averting future SARS-CoV-2 infections, hospitalizations, long-term sequelae, and death. Primary vaccination, additional doses, and booster doses are recommended for all eligible persons. Additional future recommendations for vaccine doses might be warranted as the virus and immunity levels change." 46
- e. The other papers in this paragraph were publish in 2022 and 2023.

Specific Responses to "Background: Breakthrough Covid-19 Infections as Vaccine Failure" Section of Dr. Risch's Report

- 30. **Risch Rep. at pg. 5:** "At the beginning of the vaccine roll-out, the initial randomized controlled trial (RCT) studies of vaccine efficacy claimed them to be 94-95% effective against symptomatic infection (<u>Polack et al., 2020</u>; <u>Baden et al., 2021</u>). These numbers imply that 5- 6% of vaccinated people will get breakthrough infections, comparable to unvaccinated individuals." **Dr. Lynch's response:**
 - a. This is not what those RCTs showed. The RCTs used for FDA EUA showed that being vaccinated was associated with an 94% to 95% reduction in the risk of infection compared to an unvaccinated person. Dr. Risch's statement implies a misunderstanding of basic epidemiology. For example, if, at some point in the pandemic, an unvaccinated person has a 20% risk of infection, the risk to a vaccinated person is ~5% of that risk, so ~1% risk of infection. Dr. Risch implies that if 95% of people don't get infected then 5% do get infected. For this to work, every single person would need to have an exposure event capable of causing an infection. At no time during the pandemic was there a 100% infection rate for any group. The 95% effectiveness is relative risk reduction, not an absolute risk reduction. The latter would vary throughout the pandemic based on how infectious a variant was and how many infections were prevalent.
 - b. To imply that vaccinated people got infected at the same rate as unvaccinated people makes absolutely no sense and contradicts Dr. Risch's statement's elsewhere in this document (see paragraph starting with "On September 10, 2021..." just below the above statement).
- 31. **Risch Rep. at pg. 5:** "In later PR reports, the manufacturers reported "real-world" vaccine efficacies at <u>90-91</u>%, or that about 10% of vaccinated people would get breakthrough infections." **Dr. Lynch's response:**
 - a. For reasons that I don't comprehend, Dr. Risch refers to large, peer-reviewed studies from multiple countries that demonstrated high level vaccine

⁴⁵ See https://www.factcheck.org/2021/04/scicheck-vaccines-benefit-those-who-have-had-covid-19-contrary-to-viral-posts/

⁴⁶ See https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm

- effectiveness as "PR reports" (see Lynch expert report ¶25). 47,48,49,50
- b. Dr. Risch again misinterprets the results of these studies. On a per person level, the risk of infection is reduced by ~91% to 92% *compared to* an unvaccinated person. It is not an absolute risk of infection.
- 32. **Risch Rep. at pg. 5:** "Even these efficacy claims were spuriously high, because these and other vaccine efficacy studies improperly did not attribute incident Covid-19 cases occurring within 7-21 days after vaccination to the vaccinated arm of the trial, and in some instances, they were attributed to the unvaccinated arm." **Dr. Lynch's response:**
 - a. This sentence implies a lack of understanding of basic immunology. Virus specific immunity, mediated by B-cells that makes antibodies and T-cells, takes several weeks to develop. The COVID-19 vaccines stimulate these arms of the immune response. As a result, the impact of vaccine-mediated immunity takes weeks to be able to measure. This is a standard approach for all vaccine studies and is not controversial.
 - b. At the end of this paragraph, Dr. Risch cites a paper by Neil, et al to support this claim. This paper is a preprint and has not been peer reviewed or published in any journal. The UK Office of Statistics Regulation also responded to the authors informing them that the data set that was used for the paper was not appropriate for their analysis.⁵¹ Notably, Dr. Risch cites this paper 6 times in his response report despite these facts.
- 33. **Risch Rep. at pg. 6:** "By late 2021, about 90% of the general population had either had Covid-19 infection (about 25%) or had been vaccinated against it (another 65%; <u>Jones et al., 2022</u>; figure, below), thus for many if not most individuals, by that time, exposure per se would not have resulted in clinical infection, and thus not transmission." **Dr. Lynch's response:**
 - a. Again, these are data that became available in spring of 2022, making any points by Dr. Risch retrospective. Regardless, among blood donors (the population evaluated in this study), there was a clear association between the proportion of fully vaccinated people and infection rates between January and December of 2021, as shown in Figure 2 from the same paper:

4'

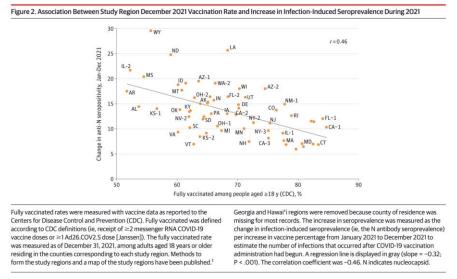
⁴⁷ See Pfizer and BioNTech Confirm High Efficacy and No Serious Safety Concerns Through Up to Six Months Following Second Dose in Updated Topline Analysis of Landmark COVID-19 Vaccine Study, Pfizer (April 1, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious.

⁴⁸ *Ibid*.

⁴⁹ See Berkeley Lovelace, Jr., Moderna says new data shows its Covid vaccine is more than 90% effective against virus six months after second shot, CNBC (April 13, 2021), https://www.cnbc.com/2021/04/13/covid-vaccine-moderna-says-new-data-shows-its-90percent-effective-six-months-after-second-dose.html.

⁵⁰ See Kathy Katella, Comparing the COVID-19 Vaccines: How Are They Different, Yale Medicine, Aug. 26, 2021, https://www.yalemedicine.org/news/covid-19-vaccine-comparison.

⁵¹ *See* https://osr.statisticsauthority.gov.uk/correspondence/ed-humpherson-to-norman-fenton-martin-neil-clare-craig-and-scott-mclachlan-ons-deaths-by-vaccination-status-statistics/



- b. Around the time of the City's vaccine mandate and similar vaccine mandates in the United States, ~60% of eligible individuals had been vaccinated. It was unknown what the immune status of the ~40% of adults who were not vaccinated was and because the vaccines were not yet approved for those under 18 years of age, what the immune status of all children was.
- c. Dr. Risch's analysis fails to explain is and is contradicted by the massive increase in COVID-19 cases, hospitalizations, and deaths in January of 2022.
- 34. **Risch Rep. at pg. 6:** "Generally, the stated goals of Covid-19 vaccination mandates have been, in various instances, to prevent public exposures to the virus. However, vaccination mandate policies should have sought to attempt to prevent the substantial *transmission* of Covid-19 infection. Exposure to Covid-19 is not the same as transmission, and this is not a facile distinction. Exposure is only relevant to the degree that it results in transmission, but transmission is the crucial endpoint, for that is, by definition, the spread of the infection from an infected person to exposed susceptible individuals." **Dr. Lynch's response:**
 - a. Employment-based vaccination mandates are designed to increase the proportion of people in a specific group who are vaccinated and as a result reduce harm to that person, their co-workers, and, where applicable, members of the public. By reducing the risk of infection, the person who is vaccinated is safer as are those around them. I agree that movement of infection from one person to another is a multi-step process.
 - b. A person must be exposed to the virus, that virus then infects that person. Once infected, some individuals will develop a disease process and some will not. In either case, there is a risk of transmitting the pathogen to another person or persons. If a vaccinated person has a breakthrough infection, the risk of transmission is decreased, which reduces exposures. If the exposed person is vaccinated, the risk of infection is reduced compared to an unvaccinated person, which in turn reduces the risk of exposing more individuals. At both the individual level and the population level, vaccinations dramatically reduce the spread of COVID-19.
- 35. **Risch Rep. at pg. 7:** "Contraindications to getting vaccinated against Covid-19 are rare. According to public <u>CDC guidance</u> at the time, the medical conditions putting people at high risk of adverse infection outcome are not contraindications to getting vaccinated. The only contraindication is "History of a severe allergic reaction (e.g.,

anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine." Such reactions are estimated to affect about one person in 100,000 (<u>Blumenthal et al.,</u> 2021)." **Dr. Lynch's response:**

- a. I agree with Dr. Risch's opinion. The COVID-19 vaccines are very safe to administer.
- 36. **Risch Rep. at pg. 7:** "To my knowledge, by the latter half of 2021 and increasingly so, two doses of the Covid-19 vaccines in general use lost most of their ability to reduce risk of infection transmission (Madewell et al., 2022). In that period, the Delta variant of SARS-CoV-2 was the predominant strain in general circulation, overtaking Alpha and previous strains in May-June 2021 and then itself overtaken by Omicron strains in December 2021-February 2022 (Christensen et al., 2022). Both Delta and Omicron started with large waves of infection even with the degrees of population vaccination and post-infection immunity present at the times of their arrival waves."

Dr. Lynch's response:

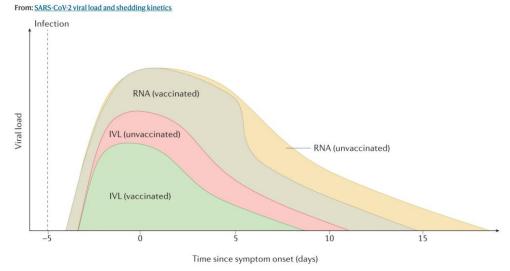
- a. As stated in my expert report and by Dr. Risch earlier in his response report, two doses of the mRNA vaccines continued to provide a substantially reduced risk of infection, between 65% and 80% depending on the study.
- b. Dr. Risch cites a study by Madewell from 2022. In the conclusions of the article, the authors wrote "Full vaccination was associated with reductions insusceptibility and infectiousness, but more so for Alpha than Delta and Omicron. The changes in estimated vaccine effectiveness underscore the challenges of developing effective vaccines concomitant with viral evolution."
- c. As has been well-described, the highest risk for infection during the delta phase of the pandemic was being unvaccinated. Vaccination continued to provide substantial protection from infection.
- 37. **Risch Rep. at pg. 7:** "Additional evidence that the Covid-19 mRNA vaccines were failing to suppress infection spread in the Delta period of 2021 is seen in the CDC blood donor infection seroprevalence data from that period (<u>Jones et al., 2022</u>; figure on previous page). The figure shows that the estimated cumulative fraction of Americans infected with Covid-19 (seroprevalence, dashed lines) was increasing through March 2021 but then started slowing as the vaccine rollout progressed, and it plateaued from March through July 2021. But then when Delta started to spread and became dominant, August through December 2021, infections were again rising like in September through December2020, in spite of the large degree of vaccination uptake that had already happened by that point (about 65% of people, the difference between the dashed and solid lines in the latter half of 2021). These empirical CDC data provide important evidence that the vaccines did reduce infection risk in the first half of 2021, but also that they increasingly failed to do so in the second half of 2021."

Dr. Lynch's response:

- a. As Dr. Risch point out in his analysis of herd immunity (paragraph 23 in this document), the R_0 of the delta variant was ~6. Using standard epidemiological calculations, approximately 83% of people would need to be immune to control the pandemic in each area.
- b. In fact, COVID-19 rates did decrease in the late summer, fall and early winter of 2021 despite the large number of people who were not vaccinated. Infection rates remained stably elevated compared to the summer of 2021 due to infections in this population.
- c. Sixty-five percent of people vaccinated was far below the goals of public health professionals and well below theoretical herd immunity levels.

- d. Dr. Risch is correct to state that vaccination did reduce infection risk in the first half of 2021. However, the second part of that sentence is incorrect. All available data show that being vaccinated was associated with a reduced risk of infection compared to an unvaccinated person even into the omicron period in December 2021 and January 2022.
- 38. **Risch Rep. at pg. 7:** "In order to transmit the Covid-19 infection, a person must first be infected. That infection may or may not be recognized as symptomatic. Vaccine effects on getting symptomatic Covid-19 infection were studied by the manufacturers and in numerous post-marketing RCT studies. However, vaccine effects on infection transmission were explicitly not studied by the vaccine manufacturers in their RCT studies (<u>Terhes, 2022</u>). To clarify, I am referring to the effect of vaccination on infection source control, i.e., whether previous vaccination reduces the infected person's risk of secondarily transmitting the infection to others. Because of the requirement first to be infected, vaccine effects on transmission might seem to correlate with vaccine effects on infection risks, but they are not the same and require independent empirical data." **Dr. Lynch's response:**
 - a. I agree that the chain of infection requires exposure to an infected person (Person A to Person B), infection (Person B), then transmission to another person or persons (from Person B to C, D, E, etc.)
 - b. Vaccination reduces the risk of infection in Person A.
 - c. Vaccination reduces the risk of transmission from Person A to Person B.
 - d. Vaccination reduces the risk of infection in Person B.
 - e. Vaccination reduces the risk of transmission from Person B to Persons C, D, E, etc.
- 39. **Risch Rep. at pg. 8:** "Published July 31, 2021, infected persons with Covid-19 in the Delta period were found to have similar viral loads, whether or not they had previously been vaccinated (<u>Riemersma et al., 2021</u>). It was later observed that infected vaccinated individuals "clear[ed] detectable infections roughly 27% sooner than unvaccinated individuals" (<u>Puhach et al., 2023</u>)." **Dr. Lynch's response:**
 - a. I agree with Dr. Risch's point that vaccinated people with breakthrough infections clear detectable infections faster than unvaccinated people. By clearing infections faster, being vaccinated reduces the risk of infecting other people in all settings, including work, home, and in public settings.
 - b. People who are vaccinated also have lower infectious viral loads compared to unvaccinated people (See figure below). These viral loads also clear faster compared to unvaccinated people.⁵² These facts indicate a lower risk of transmission.

⁵² See Puhach, O. et al. Infectious viral load in unvaccinated and vaccinated individuals infected with ancestral, Delta or Omicron SARS-CoV-2. Nat. Med. 28, 1491–1500 (2022).



Similar RNA viral loads were detected in vaccinated and unvaccinated patients infected with the Delta variant of concern during the first 5 days post-onset of symptoms. However, faster clearance of viral RNA was shown in vaccinated patients. Infectious viral loads (IVLs) were significantly lower in vaccinated individuals and declined faster than in unvaccinated individuals infected with Delta. Dynamics of viral loads in vaccinated individuals may vary widely in case of infection with another variant. Details of the underlying studies used to generate Fig. 4 can be found in Supplementary Table 3.

- 40. **Risch Rep. at pg. 8:** "Starting April 2021, CDC was monitoring Covid-19 vaccine breakthrough cases. The monthly data from April through December 2021 were initially made <u>publicly available</u> October 21, 2021 (and still are). The table above provides the CDC data on numbers of breakthrough infections, along with the CDC's estimated monthly cumulative numbers of Americans receiving the Covid-19 vaccinations. By the end of 2021, almost 6 million vaccinated people had become infected according to these data. This number comprises 4.3% of the 140 million Americans who had been fully or partly vaccinated by that time. Among fully vaccinated individuals, the breakthrough infection risk was 3.65%." **Dr. Lynch's response:**
 - a. By the end of 2021, ~62% of the U.S. population, or 205,811,394 people, were fully vaccinated
 - b. Using Dr. Risch's table, 5,105,414 fully vaccinated people had a breakthrough infection by the end of 2021. This is 2.4% of all vaccinated people, not 3.7%.
- 41. **Risch Rep. at pg. 9:** "Thus, it is clear that at the time the Washington state and Issaquah city employee Covid-19 vaccine mandates were enforced in 2021, appreciable risks of breakthrough infections were evident, making the vaccines substantially imperfect for the supposed role of reducing infection risk, and data supporting this observation were publicly available at the time." **Dr. Lynch's response:**
 - a. This is an opinion, not a fact. Using Dr. Risch's own data table, only 2.4% of vaccinated people experienced a breakthrough infection by the end of 2021. That means that 200,871,921 fully vaccinated people did not have an infection. One could argue that an intervention that prevents 97.6% of harm events is highly effective.

Specific Responses to "Background: General Comments on Covid Transmission Risks Among Vaccinated and Unvaccinated" Section of Dr. Risch's Report

42. Risch Rep. at pg. 9: "Washington State Department of Health knew throughout the

Delta period of the second half of 2021, that large numbers of Covid-19 breakthrough infections were occurring in vaccinated individuals in the state. The figure below shows that during this period, roughly 25% of all registered Covid-19 cases were breakthrough infections, more than 80,000 (Washington State Department of Health, 2022a). In addition: "From January 17, 2021 - January 1, 2022, there have been 123,365 vaccine breakthrough cases identified in Washington State. To date, more than 4.8 million people in Washington state are up to date on their vaccines. The breakthrough cases represent a small portion, about 2.5% of the vaccinated population." (Washington State Department of Health, 2022b)." Dr. Lynch's response:

- a. This is consistent with the number that I calculated in ¶40 above. A very small proportion of vaccinated people in Washington state had a breakthrough between April 2021 and December 2021.
- 43. **Risch Rep. at pg. 9:** "While there has been some serious discussion about the poor and unreliable quality of Washington State Department of Health statistics (<u>Knopik, 2024</u>), the 2.5% breakthrough figure is reasonably comparable to the 3.65%-4.3% estimated by <u>CDC</u> data." **Dr. Lynch's response:**
 - a. The Washington State Department of Health COVID-19 data are consistent with many other data sources including health systems, local health jurisdictions (Public Health-Seattle & King County), other states, and the CDC. As a result, there are no "serious discussions about the poor and unreliable quality of Washington State Department of Health statistics."
 - b. The document cited by Dr. Risch was written by Clifford Knopik. It is a nonpeer reviewed policy paper that is hosted on an anti-COVID vaccine propaganda website called "Science, Public Health Policy and the Law".
 - c. Members of the editorial board of this website include individuals who have their American Board of Internal Medicine certifications revoked for spreading COVID-19 mis- and dis-information. One of those editors, Dr. Peter McCullough, is the Chief Medical Officer at the same supplement company that Dr. Risch is the Chief Epidemiology Officer of (The Wellness Company).

Specific Responses to "Potential Risk Burden Posed by Plaintiff" Section of Dr. Risch's Report

44. **Risch Rep. at pgs. 9-10:** "In the present case, Defendant was required by public health principles to evaluate the risks inhering to both possible outcomes of their termination decision (terminate the Plaintiff or not). They only allowed one side, and only partly, an infection relative risk of 4.6 according to CDC) if she had stayed employed. This action therefore constitutes public health malpractice and was unprofessional. What was needed to have been done was to calculate the following standard public health calculations: Risk of Covid-19 infection occurring during calendar year 2021 for 2-dose vaccinated individuals: 5,105,414/139,768,554 = 3.65% (CDC data above, page 9). Total number of Issaquah police officers: 38. Estimated number of vaccinated Issaquah police officers at risk of getting Covid-19 infection after the mandate was enforced: 38-1=37. Estimated number of Covid-19 infection after the mandate was enforced: 37*3.65% = 1.35. Risk of Covid-19 infection occurring during calendar year 2021 for unvaccinated individuals: 3.65%*4.6 = 16.8%. Estimated number of Covid-19 infections in 2021 in the unvaccinated Plaintiff at risk of getting Covid-19 infection

before through after the mandate was enforced: 16.8%*1 = 0.168. Share of total infection burden by Plaintiff had she remained employed by the Gambling Commission in her same position and roles: 0.168/(1.35 + 0.168) = 11%." **Dr. Lynch's response:**

- a. Dr. Risch's proportion of breakthrough cases is incorrect. See ¶ 21 of this report. Per the report that Dr. Risch cites, approximately 2.5% of fully vaccinated people in Washington State were infected by the end of 2021.
- b. How many or what proportion of fully vaccinated people would experience a breakthrough infection by the end of 2021 was unknown at the time of the City's vaccine mandate's implementation, so this analysis could not have applied to any decision making.
- c. How does Dr. Risch know that only one person would not be vaccinated? My understanding is that at the time of the City's vaccine mandate, no one had any information on what number or proportion of the Issaquah police officers (or office administration and other support personnel) would seek accommodations for a medical or religious exemption.
- d. Policies like the City's vaccine mandate cannot be updated based on the number of people seeking exemptions in each sector, department, or area. The requirements must apply to all impacted staff equally.
- e. The City's vaccine mandate did not describe any threshold, number, or proportion of employees who should be vaccinated.
- f. During October and November of 2021 unvaccinated people had <u>13.9 times</u> the risk of infection compared to vaccinated people, not 4.6 times the risk.⁵³
- g. Dr. Risch's analysis, besides using incorrect data, also assumes that an infected person's risk to others is spread uniformly across an organization. My understanding is that the Plaintiff worked in multiple locations with coworkers, incarcerated individuals, and members of the public. The risk of having an unvaccinated person was distributed to all those groups, spaces, and encounters, including to people in jail and members of the public who may have had no choice to protect themselves.
- h. Thus, this analysis is not applicable to this case and is not relevant to any assessment for accommodation.
- 45. **Risch Rep. at pg. 11:** "In my professional epidemiologic opinion, this fraction of absolute risk for the Plaintiff, 11% of the total infections, was not actionable, because the City took in stride and <u>did not mandate booster doses</u> for the vaccinated employees in spite of all of the breakthrough infections occurring and their 8-fold greater infection numbers. **Dr. Lynch's response:**
 - a. Even if Dr. Risch's above calculations was correct, for one person in the department to be responsible to ~10% of the infection burden is high. And this number does not consider the risk of transmission to other employees, incarcerated people, or members of the public. Each of those infections could lead to COVID-19, lost days of work or school, hospitalization, long COVID, or death. In addition, each of infected person can then go on to infect others. By reducing infections and transmissions, vaccination dramatically reduces all of these risks.

⁵³ See Johnson, A. G. et al. COVID-19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults with and Without Booster Doses During Periods of Delta and Omicron Variant Emergence — 25 U.S. Jurisdictions, April 4–December 25, 2021. *Morb. Mortal. Wkly. Rep.* 71, 132–138 (2022).

- 46. **Risch Rep. at pg. 11:** "According to these guidelines, just the assertion that Plaintiff posed an excess Covid-19 infection risk (e.g., 4.6-fold) is insufficient to establish the degree (i.e., the *undue*) of hazard. This falls into the category, speculative or hypothetical hardship, that the EEOC guidelines prohibit, because Defendants (and Dr. Lynch) have given no baseline absolute risk over which the increased relative risk applies." **Dr. Lynch's response:**
 - a. During October and November of 2021 unvaccinated people had 13.9 times the risk of infection compared to vaccinated people, not 4.6 times the risk.⁵⁴ I suggest that accommodating a situation that increases a hazard (up to and including death) approximately 14-fold is unacceptable to most workers and organizations.
 - b. Dr. Risch provides his interpretation of EEOC guidelines despite having no legal background, experience in occupational health, or a history of accommodation evaluation for any reason.

Specific Responses to Section of Dr. Risch's Report Regarding Expert Report of Dr. John Lynch

- 47. **Dr. Lynch's original report statement**, "COVID-19 is a disease that can result in serious illness or death."
 - a. **Dr. Risch's reply** (**Risch Rep. at pg. 12**), "This is a generic hypothetical statement calculated to create anxiety, rather than a statement of scientific fact. In general, statement of how something "can" happen have no relevance to statements about the ways that things "do" happen. The <u>overall mortality for Covid-19 infection</u> has been less than 0.1% across the age span, and most of this mortality is concentrated in identifiable individuals who can be specifically addressed, rather than pandemic management having to inflict major burdens on the great majority of the general public." **Dr. Lynch's response:**
 - i. A death toll, in the U.S. alone, of well over 1.2 million people, including children, parents, spouses, relatives, friends, and co-workers is not a "generic hypothetical statement". This is not something that "can" happen. It did happen. Regarding Dr. Risch's using of infection fatality rate of 0.1%, a small percentage of a large number is still a large number.
 - ii. When Dr. Risch states "identifiable individuals who can be specifically addressed" it sounds like he is echoing recommendations by the Great Barrington Declaration to somehow hide away older adults and people with risks for disease progression. This declaration never described how this would happen and has since been discredited.⁵⁵
 - iii. I do not understand Dr. Risch's comment that the "great majority" of the population shouldn't take on burdens associated with the responding to and limiting as much as possible the harms of the pandemic. I would posit that is what being part of a community means.
- 48. **Dr. Lynch's original report statement,** "A subset of those with severe disease will die. As of September 26, 2024, over 1.2 million people in the U.S. have died due to COVID-19."

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⁵⁴ Ibid

⁵⁵ See https://blogs.bmj.com/bmj/2021/09/13/covid-19-and-the-new-merchants-of-doubt/

- a. **Dr. Risch's reply (Risch Rep. at pg. 12),** "This is a bland evasion of the fact that the great majority of deaths occurred in the identifiable group of elderly people with various specific comorbidities (obesity, diabetes, chronic heart or kidney disease, severe immunodeficiency, cancer, etc.)." **Dr. Lynch's response:**
 - i. Dr. Risch's comment seems to suggest that persons with common comorbidities, such as obesity, have less value, such that we should not be concerned about their premature deaths due to COVID-19. As a healthcare worker and physician, I disagree.
- 49. **Dr. Lynch's original report statement,** "There was (and remains) wide consensus among public health officials that developing an effective COVID-19 vaccine was crucial to returning to some semblance of 'normal life.'"
 - a. **Dr. Risch's reply** (**Risch Rep. at pg. 12**), "This is a statement about what people believe, not about how nature behaves. This statement ignores the large degree of post-infection natural immunity (>87% of Americans according to CDC) that returned at least that much of the population to "normal life." **Dr. Lynch's response:**
 - i. The statement that I made is exactly what scientists and public health experts wrote and spoke. Science is about investigating and then predicting how nature behaves in specific conditions.
- 50. **Dr. Lynch's original report statement,** "The COVID-19 vaccines have been held to the same rigorous safety and effectiveness standards as all other types of vaccines in the United States."
 - a. **Dr. Risch's reply** (**Risch Rep. at pg. 12**), "This statement is absurd. The vaccines never had any medium-term or long-term safety testing. Before approvals, they never had any transmission testing. They never had any carcinogenicity testing. The medium-term safety evaluations from the original RCTs were corrupted by the inappropriate vaccine uptake of the placebo groups. The vaccines available commercially in the US have only had EUA approvals not formal BLA approvals—the products that were BLA approved were not commercially released. The commercially available vaccines have substantial DNA fragment contamination, well exceeding FDA limits (Kämmerer et al., 2024; Wang et al., 2024)." **Dr. Lynch's response:**
 - i. The mRNA and J&J vaccines underwent all the standard steps for vaccine approval. I am not sure what "medium-term" and "long-term safety testing" Dr. Risch recommends in the middle of a pandemic when there is no safety signal of concern in nearly 100,000 study participants?
 - ii. Transmission testing is not a standard part of vaccine effectiveness studies. To study transmission, investigators would need to recruit not only participants but would also need to track people that the study participants expose. Those who are exposed would then need to be tracked and tested. Considering the heterogeneity of how exposures work and who could be exposed in each study participants life (work, home, etc.) and incorporating what non-pharmaceutical interventions (ex. masking) each person uses, transmission studies are extraordinarily difficult.
 - iii. There was no concern for any type of carcinogenicity in any phase of the vaccine studies. This has borne out since the EUAs were approved

- as there has been no association with any type of cancer of any type after the administration of billions of doses of COVID-19 vaccines.
- iv. Both the Moderna and Pfizer vaccine products received FDA Biologics License Application (BLA) approval. The Pfizer BLA was in August 2021 and the Moderna BLA was granted in January 2022.
- v. Dr. Risch's statement that the vaccines have "substantial DNA fragment contamination" is not true. He cites a paper from, again, an anti-COVID-19 vaccine propaganda website titled "Science, Public Health Policy and the Law". This paper has not been peer-reviewed and is not available in the global repository of biomedical research literature (NIH's PubMed). The study by Wang, et al, was published in 2024 in The Journal of High School Science (not available in PubMed either). The authors refer to studying "experimental mRNA vaccines" without any reference to commercially available products, lots, or similar. There are no studies indicating any contamination of the Pfizer or Moderna products.
- vi. Billions of doses of the COVID-19 vaccines have been administered with the most intense adverse event reporting, tracking, and researching of any therapeutic in human history.

51. Dr. Lynch's original report statements regarding efficacy of the Pfizer, Moderna and J&J COVID-19 vaccines.

- a. **Dr. Risch's reply (Risch Rep. at pg. 12),** "These studies were misanalyzed as <u>Neil et al.</u> have shown, because of excluding or misattributing infections occurring within 7-21 days of vaccination." **Dr. Lynch's response:**
 - i. As stated earlier in this document, the article by Neil and colleagues has not been peer-reviewed and has not been published in any journal despite having been presented as a preprint since March of 2024. Excluding infections in vaccinated study participants in the 7-21 days after administration is standard practice because it takes that long for the vaccines to generate a protective level of immunity.
 - ii. Mr. Neil's academic webpage (School of Electronic and Electrical Engineering and Computer Science, Queen Mary, University of London, UK) has no references to COVID-19 or vaccine research, epidemiology, or public health.
- 52. **Dr. Lynch's original report statement,** "These positive clinical results held true in the real world after the EUAs were issued. In April 2021, Pfizer announced that its vaccine had 91.3% efficacy against COVID-19, based on how well it prevented symptomatic COVID-19 infection seven days through up to six months after the second dose. Similarly, Moderna announced in April 2021 that its vaccine had greater than 90% efficacy against cases of COVID-19."
 - a. **Dr. Risch's reply** (**Risch Rep. at pg. 13**), "These claims, though undermined by the Neil et al. arguments, nevertheless, allow that about 10% of vaccinated individuals would get breakthrough infections comparable to unvaccinated people. Dr. Lynch's cited estimate of 64% vaccine efficacy (par. 71) allows that 36% of vaccinated individuals would get breakthrough infections comparable to unvaccinated people." **Dr. Lynch's response:**
 - i. Dr. Risch again misinterprets basic epidemiological data. The cited estimate of a 64% reduced risk of infection in vaccinated vs unvaccinated people does not mean that 36% of vaccinated people get

infected. This is epi 101. At no time do 100% of people get infected regardless of their vaccination status. The number is a risk reduction compared to the unvaccinated group, not an absolute risk. For example, is there is a 10% risk of infection for an unvaccinated person at a given time, the risk to a vaccinated person would be $\sim 0.7\%$.

- 53. **Dr. Lynch's original report statement,** "the only group for whom the Pfizer and Moderna vaccines (together, the "mRNA vaccines") are currently contraindicated are those acutely allergic to their ingredients—specifically polyethylene glycol or polysorbate—which is estimated to occur in only 2.5 to 11.1 cases per 1 million doses."
 - a. **Dr. Risch's reply** (**Risch Rep. at pg. 13**), "I thank Dr. Lynch for confirming my observation that contraindication to taking the Covid-19 vaccines is rare, about 1 in 100,000 people (<u>Blumenthal et al., 2021</u>). This means that virtually everyone in the population could have freely chosen to take the vaccines to protect him or herself." **Dr. Lynch's response:**
 - i. I have no idea why Dr. Risch relates these 2 comments. The fact that the vaccines are safe as well as effective provides ethical support for the City's vaccine mandate.
- 54. **Dr. Lynch's original report statement,** "COVID-19 vaccines continue to be the best tools available to prevent symptomatic COVID-19. The extremely high effectiveness of the vaccines in preventing symptomatic infections was important for slowing the spread of COVID-19."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 13),** "I discuss post-infection immunity above, pages 4-5. Dr. Lynch seems stuck in stale data here. As the CDC seropositivity data show (above, page 6), the Covid-19 vaccines were associated with preventing infection spread in the first half of 2021, but not in the second half of 2021 and thereafter." **Dr. Lynch's response:**
 - i. Dr. Risch persists in simply splitting 2021 into 2 halves. This is not a valid assumption or perspective. During the delta phase that lasted until the end of 2021, being vaccinated reduced the risk of symptomatic infection by between 65% and 80% compared to an unvaccinated person. These were the data that the City of Issaquah and Washington State had at the time of the City's vaccine mandate.
- 55. **Dr. Lynch's original report statement,** "People should get vaccinated regardless of whether they already were infected with COVID- 19 for several reasons."
 - a. **Dr. Risch's reply (Risch Rep. at pgs. 13-14),** "Inherent in this statement is the brazen denial of the importance of post-infection immunity. The overwhelming majority of the population was destined to get Covid-19 and this fact was observable in summer 2021. People did not seek to get the infection; it happened from exposures in everyday life. Above on pages 4-5, I cite some two dozen studies showing that post-infection immunity is on average at least as strong and durable as vaccine immunity, and that the great majority of these studies had been published prior to the mandate Proclamation." **Dr. Lynch's response:**
 - i. There is no denial of the immune response following infection. There is the fact that in 2021 (and to this day), the duration of immunity following infection is variable and is not predictable. Dr. Risch does not and could not claim that a person infected in March 2020 had the same level of protection in October 2021 as a person infected in

- September 2021 because there were no data to support such a claim.
- ii. There is no downside to vaccination for survivors of COVID-19. As described in my expert report, hybrid immunity appears to be the strongest kind of immune response.
- iii. In the absence of vaccination, the immune response in survivors would also wane, resulting again in their increased risk of infection.
- 56. **Dr. Lynch's original report statement,** "Other studies have found stronger immune response with vaccination after infection with COVID-19 [than after Covid-19 infection alone]."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 15),** "This point is completely irrelevant. No Covid-19 vaccine mandate including WA state has required any higher level of immunity beyond that accomplished by vaccination alone. It doesn't matter whether adding natural immunity gives more immunity. That is illogical." **Dr. Lynch's response:**
 - i. The point of my comment is part of a larger argument that having history of COVID-19 is not a contraindication to getting a COVID-19 vaccine and that doing so is in fact the CDC recommendation. This is supported by the available scientific data.
- 57. **Dr. Lynch's original report statement,** "The CDC and FDA do not recommend that people use antibody or serology tests, which look for antibodies from a previous infection or from vaccination, to assess the need for vaccination in an unvaccinated person or assess immunity to SARS-CoV-2."
 - a. **Dr. Risch's reply** (**Risch Rep. at pg. 15**), "This statement is a red herring. Post-infection natural immunity is as good or better than vaccine immunity in preventing subsequent infection. The only question for either type of immunity is how to document its existence. Vaccine cards and electronic health records do this for vaccine immunity. Recorded PCR test positivity and serum antibody positivity (not antibody levels per se) document having had Covid-19 infection. Documented having had Covid provides the evidence of immunity, not measuring circulating antibodies and showing any particular level." **Dr. Lynch's response:**
 - i. Individuals requesting accommodations due to a history of a prior infection often state that an employer can test the individual for antibodies to COVID-19. My statement is that these tests are not meant for this purpose.
 - ii. Although we know that infection-mediated immunity wanes over time, like vaccine-mediated immunity, Dr. Risch does not provide any suggested limit after which a person should be considered vulnerable again. Does he think that a person who was infected in March of 2020 is protected at the same level as someone who was infected in September of 2021?
- 58. **Dr. Lynch's original report statement,** "Having a positive [antibody or T-cell test] result indicates only that there is a high likelihood that the person was infected at some time in the past. It does not imply that the person has any protection from subsequent infection."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 15),** "Exactly the same reasoning applies to vaccine immunity. A person might have been 2-dose vaccinated in December 2020 and would still be considered as satisfying the vaccine mandate on October 18, 2021, no matter how much the circulating antibody

level had dropped in the meantime." Dr. Lynch's response:

- i. Dr. Risch appears to agree with me. Antibody tests should not be used to assess the immune status of a person. If a person has a history of infection or a history of vaccination, an antibody test will likely be positive, at least for some period. Completing a primary vaccine series continued to provide robust protection from infection, long COVID, hospitalization, and death.
- 59. **Dr. Lynch's original report statement,** "Someone who would rather get infected with SARS-CoV-2 and subsequently develop COVID-19 as a means to developing some level of temporary immunity would not be making a rational choice from a public health perspective."
 - **a. Dr. Risch's reply (Risch Rep. at pg. 15),** "In the above, I say explicitly that I do not advocate for intentional infection, and as well that this point is irrelevant in the context of what actually transpired during the pandemic. Hundreds of millions of Americans got Covid-19. They got Covid by living their lives, not by going out to seek infection. There is no rational reasoning that finds benefit in not accounting for this degree of post-infection natural immunity in public health management of the pandemic. This whole paragraph is a red herring."

Dr. Lynch's response:

- i. Again, how would Dr. Risch "account for this degree of post-infection" immunity? How many months would he allow? And after that period, should the person then get vaccinated? The fact is that we do not know how many months would work as a cut-off. And regardless of COVID-19 infection history, there is no reason not to get vaccinated. A history of infection is not a reason to request exemption from the City's vaccine mandate's requirements.
- ii. "Hundreds of millions of Americans"? By the end of April 2022, approximately 80 million people had COVID-19 out of approximately 340 million people living in the United States. Dr. Risch's statement is somewhat hyperbolic.
- 60. **Dr. Lynch's original report statement,** "Alternatives to vaccination such as regular testing, distancing, air-flow barriers."
 - **a. Dr. Risch's reply (Risch Rep. at pg. 16),** "I agree with Dr. Lynch that these approaches have not substantially reduced the spread of Covid-19. But then again, the Q4 2023 CDC seropositivity data (figure above, page 2) show that neither has vaccination reduced the spread of Covid-19. Almost everybody has had Covid-19 by now." **Dr. Lynch's response:**
 - i. There are abundant data that non-pharmaceutical interventions (NPIs) like testing (with symptoms), physical distancing, masking, and improved ventilation reduce the risk of COVID-19. The challenge is with implementation, adherence, and determination of effect size. The fact that many people have had COVID-19 is directly related to barriers and resistance to implementation and adherence of NPIs.
 - ii. There are no data that demonstrate the equivalence of being unvaccinated with any combination of NPIs compared to being vaccinated with the same combination of NPIs.
 - b. **Dr. Risch's reply (Risch Rep. at pg. 16),** "Additionally, Dr. Lynch is discussing current knowledge about the efficacy of these pandemic management measures. These measures were in widespread use in 2020-2021,

in many circumstances mandated (such as for wearing masks), and believed in that time frame to have some degrees of effectiveness. It is unreasonable to impose a current knowledge standard on issues that used only the knowledge of their times." **Dr. Lynch's response:**

- i. I am surprised by this comment given how many citations Dr. Risch implies were available at the time of the City's vaccine mandate. He refers consistently to infection rates in 2022 and 2023, and studies published in the same time frames. See paragraph 60(a) above where he refers to Q4 2023 data yet again, just before he made this comment.
- ii. The point of my statement is that there were no data that demonstrated an equivalency between wearing a mask and being vaccinated versus only wearing a mask. Masks are effective tools, but the safety of the person is vastly improved when the wearer is also vaccinated.
- 61. **Dr. Lynch's original report statement**, "Researchers from the Yale School of Public Health estimated by the end of June 30, 2021, COVID-19 vaccines prevented nearly 280,000 deaths and 1.25 million hospitalizations in the United States. By December 2021, those estimates increased to vaccines preventing over 1 million deaths and 10 million hospitalizations in the United States."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 16),** "These cited studies were modeling studies, not empirical analyses. They used parameter values such as for vaccine efficacy that did not reflect declining efficacy over time, and that overestimated the degree of vaccine efficacy because of the improper case categorization in the studies from which the values were taken (Neil et al., 2024). These modeling studies also did not adequately evaluate serious adverse events caused by the vaccines, because such data were largely suppressed at the time in order to be able to portray the vaccines as safer than they were so as to accomplish greater vaccine uptake by the public." **Dr. Lynch's response:**
 - i. Studies like the one done by the group at Yale have to use modeling to determine the impact of public health interventions like vaccinations. It is not possible to do "empirical analyses" of events that didn't happen unless there is a randomized trial, which, in the case of the COVID-19 vaccines, would be unethical.
 - ii. As explained earlier, the Neil paper is not an accepted source of information or science.
 - iii. Dr. Risch alludes to a conspiracy that "largely suppressed" serious adverse events caused by COVID-19 vaccines. Unfortunately, this is a common thread of vaccine misinformation. Dr. Risch provides no citations or proof of this allegation.
- 62. **Dr. Lynch's original report statement,** "At the time the Proclamation and City's Order requiring vaccination were announced, COVID-19 cases were spiking due to the Delta variant, despite other strategies and safety measures in place."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 16),** "Yes, these spikes occurred in spite of some 65% of the population having already been fully vaccinated, and another 25% having post-infection immunity to the virus. I have demonstrated above (page 4) that with the Delta strain of the virus estimated in July 2021 to have a reproduction number R0 of about 6, this meant that essentially everyone in the population would eventually get infected with Covid-19, and this fact was apparent in July 2021. This assessment was confirmed by the CDC seropositivity data (above, page 3) showing that by 4th quarter 2023, more than

87% of the US population had had Covid-19. One can question the utility of the Covid-19 vaccines from mid-2021 onward, given that it was then obvious that they would fail to control the spread of the infection, and this failure was publicly acknowledged by then CDC Director, <u>Dr. Rochelle Walensky</u>, on August 6, 2021." **Dr. Lynch's response:**

- i. The delta spikes were driven in large part due to the large proportion of people who had no immunity in the summer and fall of 2021, not because the vaccines were failing. The R_0 of 6 applies only to populations that are completely susceptible and is intrinsic to the virus variant, not the population. The correct epidemiological term is the *effective reproductive number* (R_e) which incorporates the proportion of people with some level of immunity in the population and so varies as conditions evolved during the pandemic. The goal was to drive R_e to less than one which would effectively stop the expansion of transmission.
- ii. At the time of the Proclamation and the City's vaccine mandate, there was no basis for understanding that "everyone" was going to get infected
- 63. **Dr. Lynch's original report statement,** "In the period leading up to December 2021, in King County unvaccinated persons were 4.5x more likely to test positive for COVID-19 than fully vaccinated persons, 32x more likely to be hospitalized, and 40x more likely to die. ... This was likely because COVID-19 vaccines provided strong protection against infection during the Delta phase, with vaccine efficacy rates up to high 80s%."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 17),** "The validity of the Washington Department of Health Covid data has been strongly criticized (Knopik, 2024). Vaccine efficacy studies have been substantially biased upwards because of the initial-period exclusion problem (Neil et al., 2024). The CDC seropositivity data and Washington state Department of Health Covid case data (cited above, pp 6 and 9) show that vaccination of a majority of the US population by then (some 65%) did not seem to slow the spread of the Delta strain. These facts contradict Dr. Lynch's claim of vaccine effectiveness against becoming infected in that period. However, Dr. Lynch's quoted test-positivity relative risk of 4.5 is similar to CDC's estimate of 4.6, but while published September 10, 2021, that estimate was based on cases diagnosed June 20- July 17, 2021."

Dr. Lvnch's response:

- i. I have already commented on the serious problems with both the Knopik and Neil documents.
- ii. I agree that the level of immunity in the population was not sufficient to stop the spread of COVID-19 in the fall of 2021. This supports the role of the Proclamation and the City's vaccine mandate to increase the proportion of people in Washington State.
- 64. **Dr. Lynch's original report statement,** "At the time the Proclamation and City's Order requiring vaccination were announced, data also suggested that vaccination offered higher protection than previous COVID-19 infection."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 17),** "This assertion is completely untrue. The CDC report cited here cherry picked its references. There were 8 studies published in 2021 comparing vaccine immunity to post-infection immunity: Shenai et al., 2021 (7 studies); and Gazit et al., 2021. These studies showed the

opposite of what Dr. Lynch is claiming: risk of infection was reduced 1.86-fold for Covid-recovered vs vaccinated uninfected people (Shenai et al., 2021), and reduced 6-fold in the Gazit et al. study." **Dr. Lynch's response:**

- i. Here is a quote from the CDC paper published in August 2021 that I cited in my report, "This study found that among Kentucky residents who were previously infected with SARS-CoV-2 in 2020, those who were unvaccinated against COVID-19 had significantly higher likelihood of reinfection during May and June 2021. This finding supports the CDC recommendation that all eligible persons be offered COVID-19 vaccination, regardless of previous SARS-CoV-2 infection status." The researchers cited papers that supported their hypothesis and informed the research question. The study used original data from Kentucky's National Electronic Disease Surveillance System for the analysis, not data from cited papers.
- ii. Additional studies available at the time supported the above research findings. 56,57
- iii. Vaccination of people who were previously infected provides higher level protection from re-infection. 58,59,60
- iv. Dr. Risch cites a systematic review by Shenai and colleagues from October 2021. One of the included studies used to support the conclusion was written by Satwick, et al, in 2021.⁶¹ That latter paper compared outcomes in people vaccinated with the ChAdOx1 (Oxford/AstraZeneca) vaccine. This vaccine was not ever used in the United States, so those data are irrelevant to this discussion. The authors also included in their analysis what appears to be a subset of studies that supported their hypothesis and excluded others (ex. the Cavanaugh paper that I cited).
- v. None of the authors of on the Shenai publication have published any epidemiological papers, on COVID-19 or any other infectious disease, before or after this single one. The senior author on the Shenai paper is Dr. Hooman Noorchashm. Dr. Norchashm has publicly claimed, without any data, that vaccinating people who have been infected is potentially harmful potentially creating a concern for a conflict in

⁵⁶ See Stamatatos, L. et al. mRNA vaccination boosts cross-variant neutralizing antibodies elicited by SARS-CoV-2 infection. *Science* 372, 1413–1418 (2021).

⁵⁷ See Lewis, N. et al. Effectiveness Associated With Vaccination After COVID-19 Recovery in Preventing Reinfection. *JAMA Netw. Open* 5, e2223917 (2022).

⁵⁸ See Lasrado, N. & Barouch, D. H. SARS-CoV-2 Hybrid Immunity: The Best of Both Worlds. J. Infect. Dis. 228, 1311–1313 (2023).

⁵⁹ See Zheng, H. et al. Meta-analysis of hybrid immunity to mitigate the risk of Omicron variant reinfection. *Front. Public Heal.* 12, 1457266 (2024).

⁶⁰ See Flury, B. B. et al. Risk and symptoms of COVID-19 in health professionals according to baseline immune status and booster vaccination during the Delta and Omicron waves in Switzerland—A multicentre cohort study. *PLOS Med.* 19, e1004125 (2022).

⁶¹ See Shenai, M. B., Rahme, R. & Noorchashm, H. Equivalency of Protection From Natural Immunity in COVID-19 Recovered Versus Fully Vaccinated Persons: A Systematic Review and Pooled Analysis. *Cureus* 13, e19102 (2021).

- interpretation of other studies.⁶²
- vi. Regarding the cited paper by Leon, et al (2022), the authors concluded, "Although the epidemiology of COVID-19 might change as new variants emerge, vaccination remains the safest strategy for averting future SARS-CoV-2 infections, hospitalizations, long-term sequelae, and death. Primary vaccination, additional doses, and booster doses are recommended for all eligible persons. Additional future recommendations for vaccine doses might be warranted as the virus and immunity levels change."
- vii. The other papers in this paragraph, including the peer reviewed version of the paper by Gazit, et al, were publish in 2022 and 2023, so the information was not available to experts or policy makers at the time of the vaccine requirement.⁶⁴
- 65. **Dr. Lynch's original report statement,** "It is important to remember that much of what we know now about the virus and the disease was unknown at the time the City's Order, King County Executive Order, and State Proclamation requiring vaccination were announced. In 2021, it was unknown exactly how the virus was transmitted and what mitigations, aside from vaccination, were the most effective."
 - a. **Dr. Risch's reply (Risch Rep. at pgs. 17-18),** "The vaccine mandate was enforced in October 2021, not when these orders were announced. Washington state and EEOC guidelines required use of the most recent scientific information available to make policy decisions. Washington State Department of Health clearly knew about the very large scale of vaccine breakthrough infections occurring in summer-fall 2021 (chart on page 9 above, showing about 20-25% of all Delta Covid-19 infections in that period were breakthrough infections, about 500 breakthrough infections per day in the state), but this knowledge apparently did not affect considerations for the October-deadline vaccine mandates." **Dr. Lynch's response:**
 - i. The time between the announcement of the City of Issaquah's order and enforcement of the requirements was fairly short. There were no substantial changes in the accepted understanding of COVID-19 dynamics during that window of time.
 - ii. Dr. Risch again manipulates the data inappropriately. When a large majority of people are vaccinated and there are breakthroughs, the absolute number may be larger among the vaccinated population. However, the rate, as discussed multiple times, was dramatically higher in the unvaccinated population. In the absence of widespread vaccine uptake in Washington State, there would have been many more infections, hospitalizations, and deaths due to COVID-19.
- 66. **Dr. Lynch original report statement,** "what we did know in 2021 and 2022 (and what is still true) is that vaccines offer protection against transmission."
 - a. Dr. Risch's reply (Risch Rep. at pg. 18), "I have discussed this at length

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⁶² See https://www.factcheck.org/2021/04/scicheck-vaccines-benefit-those-who-have-had-covid-19-contrary-to-viral-posts/

⁶³ See https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm

⁶⁴ See 1Gazit, S. et al. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity versus Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: A Retrospective Cohort Study. *Clin. Infect. Dis.*75, e545–e551 (2022).

above. In brief: the vaccine rollout was associated with reduction in infections in the first half of 2021 but substantially failed to suppress transmission in the second half of 2021 (Jones et al. CDC seropositivity data) and in 2022-2023 (CDC seropositivity data). Thus, the vaccines likely did reduce transmission in the first half of 2021, but have not done so since that time. Madewell et al., 2022 also shows that two doses of the mRNA vaccines did not reduce risk of secondary transmission in the Delta and Omicron periods." Dr. Lynch's response:

- i. COVID-19 vaccines reduced the risk of infection, transmission, long COVID, hospitalization, and death *throughout 2021*. This is not a scientifically controversial statement.
- ii. Dr. Risch continues to cite to seroprevalence data from a paper published in 2022 that does not support his statements. This study demonstrates a strong association between higher regional vaccine rates and reduced infection-induced seroprevalence.⁶⁵
- iii. The authors of the Madewell (2022) paper cited above wrote, "These findings suggest vaccination for SARS-CoV-2 transcends protection of the individual by conferring indirect protection to other household members, but the degree of protection is seemingly lower for emerging variants." Despite Dr. Risch's interpretation, the researchers analysis of their data supported the use of COVID-19 vaccines to reduce harm to the vaccinated person and to those around them.
- 67. **Dr. Lynch's original report statement,** "in a paper published in JAMA in May 2021 that tracked both symptomatic and asymptomatic healthcare workers ("HCW") in Israel, the rate of symptomatic infection in vaccinated HCW was 4.7 per 100,000 person-days and 149.8 per 100,000 in the unvaccinated cohort."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 19),** "The Shrestha cohort study of 50,000 Cleveland Clinic employees however showed that risk of Covid-19 infection significantly increased with each subsequent booster dose, not decreased. A similar inverse dose-response finding was seen in a study in Japan (Nakatani et al., 2024). Significant negative efficacy was also seen in a recent large study of the monovalent Omicron XBB 1.5 vaccine. In any event, booster doses were not required under the state mandate Proclamation, and fall of 2022 was well after the events of this legal case had transpired." **Dr. Lynch's response:**
 - i. The study by Shrestha and colleagues demonstrated a 28% reduction in individuals who were "up-to-date" on vaccines compared to those who were not "up-to-date". The vaccine that was studied was the bivalent vaccine and the circulating variant was in the omicron family. This vaccine was not available at the time of the implementation of the

⁶⁵ See Jones, J. M. et al. Updated US Infection- and Vaccine-Induced SARS-CoV-2 Seroprevalence Estimates Based on Blood Donations, July 2020-December 2021. *JAMA* 328, 298–301 (2022).

⁶⁶ See Madewell ZJ, Yang Y, Longini IM, Halloran ME, Dean NE. Household Secondary Attack Rates of SARS-CoV-2 by Variant and Vaccination Status: An Updated Systematic Review and Meta-analysis. JAMA Netw Open.2022;5(4):e229317. doi:10.1001/jamanetworkopen.2022.9317

⁶⁷ Although Dr. Risch's report states that he offered this response to the comment in Dr. Lynch's report regarding a study of asymptomatic and symptomatic transmission in Israel, it appears that he may have actually been responding to a statement in Dr. Lynch's report regarding boosters.

Proclamation and the City's vaccine mandate.

- ii. The idea that the risk of COVID-19 increase with additional doses is false. The global scientific consensus is that repeat vaccination is associated with improvement in the level of protection to the individual.
- iii. The lead author of the paper, Dr. Nabin Shrestha, in response to this claim, has stated, "Any claim that our study shows a causal relationship between getting more doses of the COVID-19 vaccine and higher risk of infection is false".⁶⁸
- 68. **Dr. Lynch original report statement,** "Vaccination against COVID-19 is fast (each dose takes about 20 seconds to administer), extremely safe, and highly effective at preventing transmission of the virus."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 18),** "Dr. Lynch has not examined or provided any analysis of vaccine harms, unlike reports by <u>Ed Dowd</u>, US and European insurance companies, and <u>Naomi Wolf</u>'s examinations of the massive internal documents on serious adverse effects of the Pfizer and Moderna vaccines." **Dr. Lynch's response:**
 - i. Ed Dowd is a known spreader of COVID-19 misinformation. He is the author of a book titled "Cause Unknown, The Epidemic of Sudden Deaths in 2021 & 2022". His claims have been refuted by multiple sources. ^{69,70,71} Dr. Risch is a co-author with this person on another book call "Canary in a COVID World: How Propaganda and Censorship Changed Our (My) World". Mr. Dowd works in investments.
 - ii. Dr. Risch provides no citation for claims of vaccine injuries among U.S. and European insurance companies.
 - iii. Naomi Wolf is an example of an extreme spreader of COVID-19 misinformation.^{72,73} Dr. Risch has appeared on podcasts with Dr. Wolf discussing "mRNA vaccine shedding" and the idea that the vaccines cause "turbo-cancers" in young people.⁷⁴
 - iv. Dr. Risch has co-authored a book titled, "Toxic Shot: Facing the Dangers of the COVID 'Vaccines'" with Byram Bridle. Dr. Bridle also spreads COVID-19 misinformation. More than 80 of his colleagues at the University of Guelph signed a letter denouncing his role in spreading misinformation.⁷⁵ Many articles have been written refuting his claims.⁷⁶ Other authors on this book include Naomi Wolf and Peter

32

⁶⁸ See https://science.feedback.org/review/cleveland-clinic-study-didnt-find-more-covid-19-vaccine-doses-causes-increased-covid-19-risk-association-alone-doesnt-imply-causation/

⁶⁹ See https://apnews.com/article/fact-checking-793439742249

⁷⁰ See https://www.reuters.com/article/fact-check/fact-check-no-evidence-that-people-aged-25-44-experienced-an-84-increase-in-ex-idUSL2N2VS1BI/

⁷¹ See https://www.factcheck.org/2023/04/scicheck-no-evidence-excess-deaths-linked-to-vaccines-contrary-to-claims-online/

⁷² See https://www.npr.org/sections/health-shots/2021/07/20/1016912079/the-life-cycle-of-a-covid-19-vaccine-lie

⁷³ See https://factcheck.afp.com/doc.afp.com.32CY4Q7

⁷⁴ See https://dailyclout.io/legendary-epidemiologist-dr-harvey-risch-on-turbo-cancers/

⁷⁵ See https://www.wormsandgermsblog.com/files/2021/07/20210709-VaccineSafety_UoGuelph.pdf

⁷⁶ See "From the Media", https://byrambridle.com

- McCullough, a known purveyor of COVID-19 misinformation.
- v. Regarding perspectives on COVID-19 vaccine misinformation and supposed harms due to the vaccines, Dr. Risch said the following on a podcast: "NIH and the Department of Defense funded dangerous, prohibited gain-of-function virus research, the engineered virus escaped from the lab, the DOD claimed that it was a bioweapon and it seized control to assert military not public health management of the pandemic, then DOD covered up the cause of the pandemic, suppressed early treatments, and forced this toxic, weakly effective vaccine, socalled vaccine, onto the population as a wartime countermeasure, not, it's not as a treatment, and without informed consent, and then hundreds of thousands of Americans subsequently died or got injured a result." He also said, "And so because all of this incompetence and malfeasance, hundreds of thousands of Americans died unnecessarily, and hundreds of thousands more were appreciably damaged, their health, they lost their health. And this was done to cover up the technically brilliant but commonsense incompetence of the elite agencies and researchers who did this."⁷⁷
- 69. **Dr. Lynch's original report statement,** "No other public health strategy could effectively meet the City's goals of maintaining critical governmental services and operations while protecting the health, safety, and well-being of its employees, customers, and the public at large."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 18),** "This statement is contrary to public health principles of weighing the costs and benefits of every intervention and policy. It says only that this one plan of mandating vaccination would be suitable, but to what quantitative end? There is no discussion of the degree to which infection transmission would be reduced and how much breakthrough infection load would occur. There is no recognition of the role that post-infection immunity could beneficially contribute. Thus, there is no understanding of the fact that Covid-zero could not be accomplished and what that would mean for policies." **Dr. Lynch's response:**
 - i. This entire statement is spin. The global scientific community supported the widespread use of COVID-19 vaccines to reduce human harm and suffering. The qualitative end was described by the three Commonwealth studies that I cited in my report that Dr. Risch so casually dismisses. Hundreds of thousands of deaths and over 1 million hospitalizations were prevented. Each of those hospitalizations and deaths started with an infection that the person got from someone else. That risk is reduced by vaccination.
 - ii. An additional study by the Brown School of Public Health estimates that if 100% of people got vaccinated in the spring of 2021, approximately 50% of the 600,000 people who died between January 2021 and April 2022 could have been saved. In Washington State alone, that would have saved 5,300 lives. If we had gotten even to 85% vaccinated, 2,100 deaths could have been prevented.
 - iii. Dr. Risch uses the term "COVID-zero" as if this goal is something

⁷⁷ See https://transcriberb.dreamwidth.org/190515.html

⁷⁸ See https://globalepidemics.org/vaccinations/

negative or bad. As a physician and public health advocate, my goal is always to reduce the risk of harm as much as possible. Zero is always a goal.

- 70. **Dr. Lynch's original report statement,** "in a paper published in JAMA in May 2021 that tracked both symptomatic and asymptomatic healthcare workers ("HCW") in Israel, the rate of symptomatic infection in vaccinated HCW was 4.7 per 100,000 person-days and 149.8 per 100,000 in the unvaccinated cohort."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 19),** "This study included infections in the pre-Delta era, when, as has been discussed above, the vaccines were associated with reduced risk of becoming infected with the virus. This benefit dramatically changed with the loss of efficacy during the second half of 2021 and thereafter. This loss of efficacy was demonstrated both by the continued large-scale infection spread throughout the population (CDC seroprevalence data above, pages 3 and 6), as well as numbers of individual studies showing that "full (i.e., 2-dose) vaccination" was substantially losing efficacy, in some studies showing negative efficacy. The <u>Shrestha cohort study</u> of 50,000 Cleveland Clinic employees showed that risk of Covid-19 infection significantly increased with each subsequent booster dose, not decreased. A similar inverse dose-response finding was seen in a study in Japan (<u>Nakatani et al., 2024</u>). Significant negative efficacy was also seen in a recent large study of the monovalent Omicron XBB 1.5 vaccine (<u>Ioannou et al., 2025</u>)." **Dr. Lynch's response:**
 - i. As stated earlier, pre-delta protection from infection was ~91% for the mRNA vaccines, during delta, which extended until the end of the year, protection was between 65% and 80% depending on how long it had been since a person was vaccinated. These are percent reduction in the risk of infection at the individual level. Throughout 2021, a vaccinated person had reduced risk of symptomatic infection compared to an unvaccinated person.
 - ii. The study by Shrestha and colleagues demonstrated a 28% reduction in individuals who were "up-to-date" on vaccines compared to those who were not "up-to-date". The vaccine that was studied was the bivalent vaccine and the circulating variant was in the omicron family. This vaccine was not available at the time of the implementation of the Proclamation and the City's vaccine mandate.
 - iii. The idea that the risk of COVID-19 increase with additional doses is false. The global scientific consensus is that repeat vaccination is associated with improvement in the level of protection to the individual.
 - iv. The lead author of the paper, Dr. Nabin Shrestha, in response to this claim has stated, "Any claim that our study shows a causal relationship between getting more doses of the COVID-19 vaccine and higher risk of infection is false". 49
 - v. The Nakatani paper was a survey of workers that had a very high risk of bias.
 - vi. The Ioannou study did not find a "significant negative efficacy" among boosted individuals. Regardless, the study occurred between October 2023 and January 2024 using a different vaccine and with a different circulating variant.

- 71. **Dr. Lynch's original report statement,** "Importantly, the choice to remain unvaccinated impacts not only the health of the person making this decision, but having more unvaccinated people in the population also increases the risk of infection for all people, vaccinated and unvaccinated."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 19),** "Here Dr. Lynch is explicitly admitting that vaccinated people are at risk of being infected. His assertion is referenced by a modeling study in CMAJ (and later, PLoSOne) by David Fisman and colleagues at the University of Toronto. The study publication caused a very large response of critical letters to the journal by numerous public health scientists, and it was fully debunked in the book, <u>Fisman's Fraud,</u> by PhD statistician Dr. Regina Watteel." **Dr. Lynch's response:**
 - i. I have continuously stated that breakthrough infections occur.
 - ii. I don't see any references to "a very large response of critical letters to the journal by numerous public health scientists". The CMAJ article had 2 letters, and I could not find any regarding the PLoSOne article. The fact the Dr. Fisman's research was published in 2 excellent scientific journals supports the author's methods and findings.
 - iii. Dr. Watteel, another author with Dr. Risch on the "Canary in a COVID World", wrote a book attacking Dr. Fisman based on these 2 articles. The full title is "Fisman's Fraud: The Rise of Canadian Hate Science." As a result of this book and associated misinformation, Dr. Fisman has receive numerous threats to his safety. He is a respected physician and epidemiologist with a long track record of research papers on COVID and other infectious disease across a spectrum of peer-reviewed research journals.⁷⁹
- 72. **Dr. Lynch's original report statement,** "It's like refusing to wear one's seatbelt just because some people still get injured in car accidents even when they are wearing their seatbelts."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 19),** "This is a completely inappropriate analogy. The correct analogy is whether I have to put large rubber bumpers on the front and back of my car because 1 in 100,000 drivers (<u>Blumenthal et al., 2021</u> estimate of people with contraindications to the Covid-19 vaccines according to CDC) doesn't or can't wear seatbelts and needs my protection. **Dr. Lynch's response:**
 - i. I don't understand Dr. Risch's analogy. The number at risk is not how many people are contraindicated to get vaccinated. The relevant number is how many people are at risk for infection, severe disease, and death due to COVID-19.
 - ii. My analogy was regarding how some individuals base their risk on personal experiences and anecdotes. To elaborate on the metaphor, if a person works only with vaccinated people and see occasional breakthrough infections, they could think that being vaccinated doesn't provide meaningful protection. Conversely, if a person works with a small group of unvaccinated people who don't get tested or don't explicitly disclose COVID-19 infection, that person could believe that unvaccinated people are not at greater for infection compared to vaccinated people. It almost goes without saying that this is why

⁷⁹ See https://pubmed.ncbi.nlm.nih.gov/?term=%22fisman+d%22&sort=date

scientific studies are required to answer these questions.

- 73. **Dr. Lynch's original report statement,** "both the vaccinated person and all of those around them are at much lower risk of infection [because of the vaccinated person's vaccination]."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 20),** "If the people around the vaccinated person desired to be at lower risk of infection, they were free (99,999 out of 100,000 of them anyway) to take the vaccination themselves. See previous paragraph." **Dr. Lynch's response:**
 - i. The fact is that many Americans decided not to get vaccinated despite the progression of the pandemic.
 - ii. Government employees have, in my opinion, an ethical obligation not to increase the risk of harm to members of the public or to negatively affect governmental operations.
 - iii. Police officers take an oath to protect the public. Infecting members of the public goes against that oath.
 - iv. Vaccination reduces the risk of transmission *and* infection. The highest risk for vaccinated people is exposure to unvaccinated people.⁸⁰
- 74. **Dr. Lynch's original report statement,** "Dixson may have been infected and asymptomatic in the past and may be in the future. She may have also had respiratory symptoms and decided not to get tested."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 20),** "This whole paragraph is speculative and hypothetical and violates EEOC guidelines on that basis. It has no place here." **Dr. Lynch's response:**
 - i. My statement was not hypothetical, as it was based on the factual information provided to me that Plaintiff stated in her testimony.
 - ii. This statement is based on the scientific data that demonstrates that (a) people who are shown to have been infected based on PCR tests may report no symptoms; and (b) that persons who contract COVID-19 but are not symptomatic may nevertheless transmit COVID-19. These facts would apply to the Plaintiff as well.
 - iii. Dr. Risch has no identified expertise as a legal or EEOC expert. To the extent that any such guidelines prohibit acting based on purely speculative or hypothetical risks, such guidelines would not be violated by acting based on public health guidance that is based on peerreviewed scientific data available at the time. Understanding the risks associated with the possibility of an unvaccinated person being asymptomatic and/or untested, and thus unaware of their positive COVID-19 status is neither speculative nor hypothetical.
- 75. **Dr. Lynch's original report statement,** "Dixson has also stated that she was "100% safe during the entire pandemic," which I understand to mean that she is asserting that she never transmitted COVID to either co-workers or the public."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 20),** "Dr. Lynch spends a long paragraph discussing biological, medical and public health considerations as to whether the Plaintiff could know that she was "100% safe." This discussion is entirely misplaced, because the Plaintiff's assertions, after the fact, are irrelevant for

⁸⁰ See Fisman, D. N., Amoako, A., Simmons, A. & Tuite, A. R. Impact of immune evasion, waning and boosting on dynamics of population mixing between a vaccinated majority and unvaccinated minority. *PLOS ONE* 19, e0297093 (2024).

considerations of her infection risk going forward at the time of her termination." **Dr. Lynch's response:**

- i. The Plaintiff's statement implied a very high level of confidence that was not based in fact. It goes to the Plaintiffs misunderstanding of her own risk of infection and transmission to other people.
- ii. In addition, the Plaintiff has no experience or expertise in infectious disease transmission or mitigations and cannot make this assessment.
- 76. **Dr. Lynch's original report statement,** "by the end of 2022, COVID-19 vaccines prevented 18.5 million COVID-19 hospitalizations and 3.2 million deaths in the U.S. alone. Attached hereto as Exhibit B is a true and correct copy of the CDC's Oct. 20, 2023, Morbidity and Mortality Weekly Report."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 21),** "These modeling results are controversial. Aside from that, 99,999 people out of 100,000 could have freely chosen to take the vaccines themselves to try to prevent hospitalization and mortality (Blumenthal et al., 2021). The state has no state interest in forcing a medical treatment on people, only in preventing virus spread. This case is not about hospitalization or mortality but about preventing workplace virus transmission, so these observations are largely irrelevant." **Dr. Lynch's response:**
 - i. Data regarding the effectiveness of COVID-19 vaccines in preventing hospitalizations and death, by reducing both infection and transmission, are relevant to preventing hospitalizations and deaths among employees and those with whom they interact in the course of performing their jobs. I see only Dr. Risch's opinion and no data or references challenging the validity of this CDC paper and the estimates quoted above. Moreover, Dr. Risch focuses on the "state" despite the fact that the mandate at issue in this case was issued by the City of Issaquah.
- 77. **Dr. Lynch's original report statement,** "Notwithstanding anecdotal observations from a workplace from late 2021 through April 2022, which may not be accurate based on asymptomatic COVID infections, an unvaccinated person was still more likely than a fully vaccinated person to contract and transmit COVID, and to experience serious illness or death from COVID."
 - a. **Dr. Risch's reply (Risch Rep. at pgs. 21-22),** "This assertion is wrong for multiple reasons. First, both CDC and Washington State Department of Health have made public their large population datasets showing how great the cumulative breakthrough infection risks were over 2021 through 2022 (cited above). These are not "anecdotal observations from a workplace." "Anecdotal" refers to observations about a person or two. Thus, the term as used here is derogatory and not scientific. Second, the risks individual-by-individual, to which Dr. Lynch is referring, are not relevant because there were many more vaccinated than unvaccinated individuals, and EEOC guidelines (of which Dr. Lynch seems unaware) state explicitly that totalities of infection risk burdens are involved in the evaluation of exemptions and accommodations, not individual-level risks per se. Finally, whether infections are asymptomatic, minimally symptomatic, fully symptomatic, etc. applies equally to recognition of infection in both unvaccinated and vaccinated workers." **Dr. Lynch's response:**
 - i. Dr. Risch's repetition does not make his arguments any more correct.

- My comment was about how an individual's perceptions of COVID-19 transmission in the workplace can lead to an incorrect understanding of risk.
- ii. Regarding breakthrough cases, if 100% of a population is vaccinated, then only vaccinated people can get infected. That doesn't mean that the vaccine doesn't work. Dr. Risch continues to focus on numbers and not rates. Rates convey risk.
- iii. There were not and are not any calculations or known thresholds that could be used to determine the "totalities of infection risk burden". If one person infects another person, that second person could have any COVID-19 outcome up to and including death. Having an unvaccinated person in the workplace, in the jail, and working with members of the public could not be accommodated to the same level of reduced risk compared to having a vaccinated person.
- 78. **Dr. Lynch's original report statement,** "I am aware that some people have expressed opposition to receiving the COVID-19 vaccines based on the use of HEK293 cells in the development or testing of the Pfizer and Moderna vaccines."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 22),** "For some reason, Dr. Lynch has omitted the salient point that that this immortalized cell line was grown from tissue taken from an aborted fetus. Apparently, there has been some recent—though uncertain—claim that the original source may not have been an aborted fetus but a miscarried one, however the traditional understanding was an abortion as the source. This has religious implications for some people. The whole point of Dr. Lynch writing this paragraph about HEK293 cells, without stating that the reason for the opposition is religious in nature, shows that he is not being forthright in characterizing this point." **Dr. Lynch's response:**
 - i. I am being perfectly forthright. I referenced "HEK293 cells" as that is the commonly used and accurate abbreviation for human embryonic kidney 293 cells. It is important for a person to have all the facts when making a medical decision. I have no objection to a person's right to refuse vaccination, for any reason, including any religious reason.
 - ii. If the reason not to get vaccinated is based on facts about what cell lines were used in the development and/or testing of the vaccine product, we should be clear and transparent about what was used and how.
 - iii. The fact is that we do not know if this immortalized cell line used cells from a spontaneous abortion (a miscarriage) or an elective abortion. That difference may be important to the person who wants to get vaccinated otherwise.
- 79. **Dr. Lynch's original report statement,** "I understand that the City's assessment of the burden on the City included the following considerations:

In making its determination, the City considered:

- Ms. Dixson's direct contact with the public on a daily basis.
- The contact Ms. Dixson had with other City employees.
- Developments in COVID-19 that increased the chances of contracting and spreading the virus.
- The cost of continued testing, both from a work efficiency and financial perspective.
- The City's plan to reopen offices to both staff and the public beginning November 1, 2021."

- a. **Dr. Risch's reply (Risch Rep. at pgs. 22-23,** "As I discussed above for paragraph 75, there is no consideration here of the basic public health principle of evaluating the risks posed by each direction of the potential decision outcome, termination or accommodation. The considerations enumerated in this paragraph have no quantitative risk evaluation. That violates the EEOC guidelines about evidence for determining undue hardship. As well, "the cost of continued testing, both from a work efficiency and financial perspective" is a red herring, because even regular testing did not provide material efficacy for reducing infection spread..." **Dr. Lynch's response:**
 - i. The quantitative consideration of risk informed the City's vaccine mandate and the Governor's Proclamation. The evaluation at the level of the City was whether an accommodation could be made for the Plaintiff that would approximate the same level of safety for her and for those around her compared to a vaccinated police officer with the same duties. The City was unable to modify her position to achieve this goal, thus an accommodation was unable to be made.
 - ii. As Dr. Risch wrote, he agrees that testing is not a mitigation tool that provided a similar layer of safety as vaccination.
 - iii. Dr. Risch again implies that his questionable assessment of the population risk should stand in for the risk associated with the Plaintiff's vaccination status and the risk to those she would interact with. The Plaintiff's risk of infection was ~14 times that of a vaccinated police officer. And that risk would recur, assuming she survived a COVID-19 infection and was able to return to work, as infection-mediated immunity eventually wore off.
- 80. **Dr. Lynch's original report statement,** regarding "Discussion of Plaintiff's job duties."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 23),** "My understanding is that Dr. Lynch is not an industrial hygienist and thus not qualified to make assertions on these points. Further, the discussion is completely irrelevant, because the 37 vaccinated officers, doing these same jobs and duties, conveyed much greater infection risks in toto as calculated above, than what Plaintiff would have done." **Dr. Lynch's response:**
 - i. As the medical director of the Infection Prevention and Employee Health programs of a large, urban, teaching hospital for the last 15 years, I have extensive experience in evaluating the risk for not only infectious diseases but also overall harm for a very large number of positions, ranging from security officers to nurses to nutrition and food service personnel.
 - ii. When considering an exemption request or need for accommodation, I evaluate an employee's job description, job environment, other information about job duties, co-workers, and other individuals who the employee may interact with. For example, an employee may need to interact with pregnant people or with neonates, 2 groups that have different risks for infection and disease progression. The evaluation for accommodation for that individual does not rely on the risk of infection for the entire population, only on that employee.
 - iii. The Plaintiff's job duties involved working with other police officers, other employees, members of the public, and people who are being

arrested, detained, or incarcerated. The risk of COVID-19 for an unvaccinated police officer is much greater than for a vaccinated police officer. As a result, the risk to co-workers, members of the public, and people being detained, arrested, or incarcerated is greater when exposed to an unvaccinated police officer compared to a vaccinated police officer.

- 81. **Dr. Lynch's original report statement,** "As explained above, at the time the vaccination policy was announced, COVID-19 cases were spiking due to the Delta variant despite other strategies in place. This was followed by the Omicron waves, which continued in this area into 2022."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 24),** "These infection waves occurred in spite of the fact that some 65% of the population had already been vaccinated, and another 25% had post-infection immunity. The vaccines were failing to control the spiking that Dr. Lynch describes, yet he is asserting that even more of the same failed recipe is needed. The September 2021 vaccine booster rollout did not prevent the large January 2022 Omicron wave. CDC in August 2022 (Massetti et al., 2022) acknowledged that the 2-dose vaccines had failed, and that booster doses had had very short-lived benefits against infection. Yet Dr. Lynch is still flogging this horse. This whole paragraph deals with unvaccinated people but ignores the greater risks posed by the much larger numbers of breakthrough infections in vaccinated people. It is a complete misrepresentation of the public health circumstances of the period." **Dr. Lynch's response:**
 - i. My statement refences the facts that cases, hospitalizations, and deaths during the delta phase were disproportionately occurring in
 - unvaccinated people. This whole paragraph deals with unvaccinated people but ignores the greater risks posed by the much larger numbers of breakthrough infections in vaccinated people. It is a complete misrepresentation of the public health circumstances of the period.
 - ii. The spike in cases due to the delta variant that I referred to above occurred at the end of August 2021. At the same time, just over 50% of Americans were fully vaccinated. The explosive number of infections, hospitalizations, and deaths due to COVID-19 in the summer and early fall of 2021 catalyzed the need to improve vaccination rates in all sectors of U.S. society.
 - iii. Dr. Risch mentions "flogging this horse" yet persists in using data from research that was not remotely available to policy makers or public health experts in 2021. The paper by Massetti in August of 2022 is a summary document that described a strategy to reduce human suffering and harm due to COVID at that time in the pandemic. Those recommendations were not applicable in the fall of 2021. For example, the drug Paxlovid was not available in the fall of 2021 but is part of the recommendations presented in this document.
 - iv. Of note, on page 2 of Dr. Risch's report, he wrote that he co-authored 2 papers that "explicate the standard understanding of early outpatient

⁸¹ See Massetti, G. M. et al. Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems — United States, August 2022. *Morb. Mortal. Wkly. Rep.* 71, 1057–1064 (2022).

COVID-19 management". Those papers recommend the use of hydroxychloroquine, azithromycin or doxycycline, favipiravir, and zinc products for COVID-19. In the medication section of this summary from the CDC COVID-19 Emergency Response Team there is no mention of any of these medications for COVID-19. All of these medications have been shown to have no effect on COVID-19. I would argue that this is a better example of futility ("flogging this horse") than Dr. Risch's objections to the data that I present.

- 82. **Dr. Lynch's original report statement,** "If an unvaccinated employee enters a work site, office, or public area, there is a greater risk of COVID transmission, leading to infection of co-workers, employees, or members of the public and carrying a significant risk of a super-spreader event."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 24),** "I show above, page 6, that in fall 2021, some 90% of the general public had vaccine or post-infection Covid-19 immunity or both. While infection transmission was still possible, this large degree of population immunity makes superspreading events very unlikely to happen. Also, Dr. Lynch's statement is speculative and hypothetical which violates the EEOC guidelines." **Dr. Lynch's response:**
 - i. If Dr. Risch's hypothesis was correct, why did the number of COVID-19 cases continue to increase through the end of 2021 and increase dramatically in January 2022?⁸² And why did hospitalizations reach the highest levels of the pandemic in January 2022?⁸³ These data do not support the assertion that "population immunity makes superspreading events unlikely to happen."
 - ii. The data cited about support the very high level of concern that health policy makers, researchers, infectious diseases physicians, and public health professionals had in the summer and fall of 2021 regarding the future of the pandemic. What Dr. Risch disparagingly refers to as "speculative and hypothetical" is what experts are asked to do in global disasters like the COVID-19 pandemic: to take steps to reduce risks of infection and death based on the best scientific data available.
 - iii. Based on available information it does not appear that Dr. Risch, during the pandemic, never had to care for a single patient with COVID-19, never had to go into a clinic or hospital overflowing with ill patients, and was never responsible for ensuring the continuation of vital public services like a police force, a town/city, or a health system. That may explain his lack of appreciation for the responsibilities public employer faces in trying to reduce pandemic infectious disease risks for employees and the public with whom they interact.
 - iv. Dr. Risch, a cancer epidemiologist, provides his interpretation of EEOC guidelines for unknown reasons.
- 83. **Dr. Lynch's original report statement,** "While transmitting COVID-19 to a coworker implicates serious issues, including the outcomes of infection in that person, and the transmission from that person to other people in their lives (including potentially higher risk family members), transmitting COVID-19 to an unsuspecting child, member of the community, or a person who has been arrested ... implicates

⁸² See https://www.statista.com/statistics/1103185/cumulative-coronavirus-covid19-cases-number-us-by-day/

⁸³ See https://ourworldindata.org/covid-hospitalizations

potentially even greater issues."

- a. Dr. Risch's reply (Risch Rep. at pg.24), "Essentially everyone could have gotten vaccinated if they had chosen to. The implication of "serious issues" is a nonsensical claim because 99,999 out of 100,000 people could have freely chosen to try to protect themselves by getting vaccinated (Blumenthal et al., 2021). This whole statement is speculative and hypothetical, which is prohibited by the EEOC guidelines." Dr. Lynch's response:
 - i. Dr. Risch's statement supports my expert report statements regarding the safety of the COVID-19 vaccinations.
 - ii. Dr. Risch's statements suggest that he does not think that COVID-19 is a potentially serious infectious disease. For example, in paragraph 8, page 12 of his report, he wrote that the fact that at least 1.2 million people died due to COVID-19 was a "bland evasion" because more older people than younger people died, suggesting that extremely high numbers of premature death of such persons is not of concern because of their advanced age. The City and the State used the available data to develop and to implement the City's vaccine mandate and the Proclamation in order to reduce COVID-19 infections, and by doing so reduce human harm and suffering, while maintaining critical governmental functions.
- 84. **Dr. Lynch's original report statement,** "Based on recommendations from the CDC, the Washington Department of Health, Public Health Seattle & King County, and my own research and understanding, it is my opinion that vaccination was and is the single best tool available for stemming the spread of COVID-19 and its variants. No other public health strategy could effectively meet the City's goals of safely providing City services while also protecting the health, safety, and well-being of employees and the public at large."
 - a. Dr. Risch's reply (Risch Rep. at pgs. 24-25), "With regard to stemming the infection spread, the CDC Q4 2023 data (top of page 3) show that all of the vaccination and boosters taken by the US population still allowed more than 87% of the population to have gotten Covid-19 anyway. That is a pretty failing grade. The vaccines began failing in mid-2021 and even with boosters still did not prevent almost the whole public from getting infected. But Dr. Lynch is extolling the supposed virtues of "the vaccines" without clarifying that the 2-dose vaccine regimen, the regimen required under the mandates in this case, totally failed as of 2022. As to other possible measures that could have been taken, the question is not vaccination but mandate. See above, paragraph 90. Dr. Lynch has only justified vaccination as a tool of public health but has provided no evidence that the addition of mandating vaccination as opposed to requesting or incentivizing vaccination would not have met the same goal. Furthermore, even with the City's mandate, Dr. Lynch does not address the fact that the separated employee, by her small number, would not have created an undue infection fraction compared to the degree of infection risk burden tolerated in stride by the whole police force, in spite of the availability of vaccine booster doses that could have been mandated to reduce this burden."

Dr. Lynch's response:

i. Dr. Risch continues to cite infection data from 2023, which is not relevant to the Proclamation or the City of Issaquah's order. Primary series vaccination rates for adults only got to around 60% by the end of

- 2021 and between 20% and 30% of people decided to get a booster vaccine. The level of immune evasion by variants in 2022 that were unknown and unpredictable could not have been part of the accommodation discussion up to and including the Plaintiff's separation.
- ii. Dr. Risch's statements speak not to vaccine effectiveness but to our failure as a society to prioritize vaccination for every eligible person in the United States. Not supporting people to get vaccinated was the "failing grade", not the vaccine itself.
- iii. Vaccine mandates are ethical and effective tools to increase vaccination rates especially when combined with reduced cost or free vaccines, education regarding the benefits of vaccination, and reduced barriers to access. 84,85,86,87,88,89,90
- 85. Dr. Lynch original report statement, regarding "Discussion of masking, distancing and testing."
 - a. **Dr. Risch's reply (Risch Rep. at pg.25),** "Not really relevant given the discussions I've written, above. None of these were necessary to be particularly effective in order that Plaintiff's expected risk would still be dramatically lower than the breakthrough infection risks posed by the large body of vaccinated staff." **Dr. Lynch's response:**
 - i. Dr. Risch does not advocate for any single or combination of non-pharmaceutical interventions for unvaccinated individuals. As explained in my report, non-pharmaceutical interventions (such as masking, testing, and social distancing) are, in themselves, insufficient to reduce the risk of infection and transmission in the workplace compared to vaccination combined with non-pharmaceutical interventions.
 - ii. Dr. Risch continues to focus on a hypothetical population risk, while ignoring the fact is that being unvaccinated posed a clearly high risk of infection compared to being vaccinated. As an unvaccinated person, Plaintiff had a higher risk of being infected. Being infected put the Plaintiff and everyone around her, including people at higher risk of infection and for disease progression. Being vaccinated could have reduced her risk of infection by 65% to 91% compared to the risk of infection if she remained unvaccinated. If she was vaccinated and

⁸⁴ See Wang, Y., Stoecker, C., Callison, K. & Hernandez, J. H. State COVID-19 Vaccine Mandates and Uptake Among Health Care Workers in the US. *JAMA Netw. Open* 7, e2426847 (2024).

⁸⁵ See Wang, Y., Callison, K., Hernandez, J. H. & Stoecker, C. Impacts of State COVID-19 Vaccine Mandates for Health Care Workers on Health Sector Employment in the United States. *Am. J. Public Heal.* 115, 344–348 (2025).

⁸⁶ See Largent, E. A. & Miller, F. G. The Legality and Ethics of Mandating COVID-19 Vaccination. *Perspect. Biol. Med.* 64, 479–493 (2021).

⁸⁷ See Lynch, J. B. Vaccine Mandates for Health Care Workers—An Effective Policy Tool for Past and Future Pandemics. *JAMA Netw. Open* 7, e2426820 (2024).

⁸⁸ See McGarry, B. E. et al. Association of State COVID-19 Vaccine Mandates With Staff Vaccination Coverage and Staffing Shortages in US Nursing Homes. *JAMA Heal. Forum* 3, e222363 (2022).

⁸⁹ See Rao, R., Koehler, A., Beckett, K. & Sengupta, S. COVID-19 Vaccine Mandates for Healthcare Professionals in the United States. *Vaccines* 10, (2022).

⁹⁰ See Juarez, R., Siegal, N. & Maunakea, A. K. The Effects of COVID-19 Vaccine Mandates in Hawaii. *Vaccines* 10, 773 (2022).

- happened to have a breakthrough infection, her risk of transmitting to other people would have also been reduced. Lastly, by being vaccinated, the risk that she would be hospitalized or die due to COVID-19 would be reduced to nearly zero, which would support the operations of an essential City of Issaquah services.
- iii. Dr. Risch continues to avoid responding to the fact that infectionmediated immunity wanes and the only way to restore that level of protection would be to either get vaccinated or to get infected again. If a person declines vaccination, they would be at risk for being infected repeatedly over time, not just once.
- 86. **Dr. Lynch original report statement,** "It is my opinion that the City's undue hardship conclusion was supported by the scientific evidence and public health data available from August 2021 to February 2022 and today. Given above-mentioned evidence and Plaintiff's job duties, ... it is my opinion that, had the City allowed Plaintiff to continue her employment unvaccinated, it would have significantly increased the risk that Plaintiff would infect co-workers and members of the public with COVID-19 or contract the virus herself." "an unvaccinated person posed materially higher risks of transmitting COVID-19."
 - a. **Dr. Risch's reply (Risch Rep. at pg. 25),** "Dr. Lynch did not do an absolute risk calculation. Therefore, he has no grounds to assert that Plaintiff's higher infection risk would have created undue hardship. A higher risk by itself is not actionable without an estimate of the absolute risk. Dr. Lynch did not do this calculation and the City did not do this calculation. Further, Dr. Lynch is not an attorney and thus has no training or expertise on which to judge the presence of undue hardship. Finally, neither "significantly" nor "materially" are quantitative amounts and they have no statistical meaning denoting any aspect of magnitude of amount. Dr. Lynch is using these terms to appear to bolster the validity of his assertions, when in fact his assertions are not based on scientific epidemiologic or public health grounds, as I have thoroughly documented above." **Dr. Lynch's response:**
 - i. During a pandemic involving a deadly virus, an employer is confronted with trying to reduce the risk of serious illness or death as much as possible, while disrupting vital public services as little as possible. For example, if an employer required that every employee worked remotely, the risk of transmission between co-workers would be near zero, assuming no other contact. But the reality is that many employers, including those providing police department services, have to work inperson, with co-workers, and with members of the public. Based on scientific data available at the time, an unvaccinated person was significantly more likely to contract and transmit COVID-19, as well as to become seriously ill or die, as compared to a vaccinated person in the same position.
 - ii. When comparing the situation of a vaccinated versus an unvaccinated person in the middle of a pandemic, there is no equivalent accommodation for an unvaccinated police officer who has to interact with co-workers (police officers and other employees), incarcerated people (who are at greater risk of infection and disease progression and may not be able to don PPE), and member so the public who may have no choice but to interact with a police officer.

- iii. In addition, it is in the City's interest to maintain a healthy and functional police force to provide essential services.
- iv. In Dr. Risch's comments on the EEOC definition, he provided his interpretation of that language even though he is not a lawyer, nor does he have any expertise in occupation health.
- v. Dr. Risch has no experience in clinical infectious disease, vaccines, healthcare operations, occupational health, or the accommodations process. He co-authors papers and books with well-known spreaders of misinformation and considers himself an expert in the field despite having research papers retracted and having none of his therapeutic recommendations included in any national or international treatment guidelines. Dr. Risch is on record as stating that the pandemic was the result of a bioweapon that was suppressed by the U.S. Department of Defense. He is currently the "Chief Epidemiology Officer" for a supplement company where he recommends "Spike Support", "Peak Metabolism", and "Natural Immunity" supplements for \$60 a bottle and a "Contagion Emergency Kit" that contains hydroxychloroquine, ivermectin, azithromycin, and oseltamivir for \$324.99.91 Selling supplements like "Spike Support" that purport to "break down spike" from COVID-19 vaccination using selenium, Irish sea moss, green tea, black seeds, nattokinase, and dandelion root.
- vi. As an infectious disease physician who has responded to the COVID-19 pandemic since January 2020, the medical director of a large, academic medical center's employee health and infection prevention programs, and the lead clinician on UW Medicine's COVID-19 Emergency Response, I have extensive experience in operations and employee vaccination programs. As described throughout my expert report and in this response, I used the available public health, scientific, and professional experience to make the above statements.
- vii. At the time of the City of Issaquah's vaccine mandate and Plaintiff's separation, it was not possible for the City of Issaquah to provide an accommodation that would have provided a similar level of safety for the Plaintiff and for her co-workers (not only police officers), individuals who would be interviewed, arrested, or incarcerated, or members of the public compared to a vaccinated officer doing the same job.

⁹¹ See https://www.twc.health/pages/dr-harvey-risch?srsltid=AfmBOoqbIfUrL-L8xfRbsB_VKPJ97JZNQH7Q4TA3OeQnm7ZIp32CEajR

Case 2:24-cv-01673-TL Document 16 Filed 05/23/25 Page 165 of 166

EXHIBIT H

Health

04.24.2025 Risch

19

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NATIONAL State -

SUMMARY

Economy

CASES AND DEATHS

VACCINATION PROGRESS

IMPACT AND RECOVERY

RELATED ARTICLES

what's the nation's progress on vaccinations?

At least 270,227,181 people or 81% of the population have received at least one dose.

